ASTRALIS LTD
Form 10KSB
March 31, 2005

U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-KSB

(Mark One)

|X| ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2004

|_| TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 000-30997

ASTRALIS LTD.
(Name of small business issuer in its charter)

Delaware	84-1508866
(State or other jurisdiction of Incorporation or organization)	(I.R.S. Employer Identification No.)
75 Passaic Avenue, Fairfield, New Jersey (Address of principal executive offices)	07004 (Zip Code)

Issuer's telephone number
(973) 227-7168

Securities registered under Section 12(b) of the Exchange Act:
None

Securities registered under Section 12(g) of the Exchange Act:
Common Stock, $.0001 par value
(Title of class)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes |X| No |_|

Check whether disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. |_|

State issuer's revenues for its most recent fiscal year. --

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of March 29, 2005, was approximately $4,868,697.

As of March 29, 2005, there were 73,173,055 shares of the registrant's common stock outstanding.

Transitional Small Business Disclosure Format (check one):

Yes |_| No |X|

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the proxy statement for the annual meeting of shareholders of Astralis Ltd., to be filed pursuant to Regulation 14A no later than April 30, 2005, are incorporated by reference into Part III of this Form 10-K.

PART I

Item 1. Description of Business

General

We are a development-stage biotechnology company primarily engaged in research and development of treatments for immune system disorders and skin diseases. We are focusing on the development of two products. Our primary product, Psoraxine(R), is an immunotherapeutic product for the treatment of the skin disease psoriasis. We are currently engaged in ongoing research and development of Psoraxine(R). We are also developing a product for the treatment of arthritis. In addition, we are engaged in research on the possible development of the technology underlying Psoraxine(R) for the treatment of other indications, such as eczema, seborrheic dermatitis and leishmaniasis.

We were originally incorporated under the laws of the State of Colorado in 1999 under the name Hercules Development Group, Inc. We subsequently changed our name to Astralis Pharmaceuticals Ltd. and, in November 2001, reincorporated under the laws of the State of Delaware under our present name. Our main office is located at 75 Passaic Avenue, Fairfield, New Jersey 07004.

Recent Developments -

Astralis Phase II Study of Psoraxine(R) for Psoriasis Did Not Meet Primary Study Endpoint

On March 14, 2005, we issued a press release to disclose the results of our Phase II study for Psoraxine(R). The Phase II study of our novel immuno-stimulatory product for the treatment of Psoriasis did not meet the primary study endpoint upon completion of the treatment phase of the study. In the study, Psoraxine(R) was found to be safe and well-tolerated. The Phase II randomized, double-blind, placebo-controlled study involved 120 patients with moderate to severe psoriasis who received intramuscular injections of Psoraxine(R). The primary endpoint of the study was a specified level of improvement of symptoms as measured in accordance with the Psoriasis Area and Severity Index (PASI), a measurement scale that ranks the severity of symptoms of patients suffering from psoriasis. Initial analysis of the preliminary data showed no statistically significant clinical improvement compared to placebo following six injections over twelve weeks of treatment. We are currently analyzing the data from our Phase II study to understand why the results differ from the long-term improvement of the more than 2,700 patients who were treated with Psoraxine(R) in pre-clinical studies and whether a different approach, including evaluating a longer course of therapy and/or modifications to the formulation, may yield an outcome that is more consistent with results from pre-clinical studies. Further details about the study will be available when all data analyses are complete.

SkyePharma Acquired 11,160,000 Additional Shares of Astralis

Pursuant to a Stock Purchase Agreement, dated December 29, 2004, between SkyePharma, Mike Ajnsztajn, our former Chief Executive Officer and former member of our Board of Directors, and Gaston Liebhaber, a former member of our Board of Directors, effective March 3, 2005, SkyePharma purchased 11,160,000 shares, collectively, of our common stock from Mr. Ajnsztajn and Mr. Liebhaber. As a result of this purchase, SkyePharma owns 36,360,000 shares, or 49.8%, of our

issued and outstanding common stock. See Risk Factor entitled "One of our existing stockholders can exert control over us and may not make decisions that further the best interests of all stockholders" for a discussion of the possible consequences of SkyePharma's ownership of our common stock.

Limited Working Capital

Based on our current plans, we believe that we have sufficient funds to meet our operating expenses and capital requirements through approximately the 2nd quarter of 2005. We will need to raise additional funds to continue our operations following that period. Furthermore, substantial additional funds will be needed in order to fund our continued efforts to obtain FDA approval of Psoraxine(R), especially given the failure of our Phase II study to meet its primary endpoint.

Psoriasis

Psoriasis is a chronic inflammatory skin disorder of currently unknown origins that generally lasts a lifetime and for which there is presently no known cure. Researchers believe that psoriasis may be caused by the immune system sending faulty signals that affect the growth cycle of skin cells. As a result, skin cells accumulate on the surface of the body faster than normal. In people without psoriasis, skin cells mature and are shed approximately every 28 days. In psoriatic skin, the skin cells mature over a period of approximately three to six days.

The symptoms of psoriasis include scaly skin and inflammation occurring on a cyclical basis, with periods of remission and relapse. There are five types of psoriasis. The most common form, appearing in approximately 80% of individuals suffering from the disease, is plaque psoriasis. The other forms are guttate, inverse, erythrodermic and pustular psoriasis. Psoriasis typically does not prevent individuals with the condition from functioning normally. However, the pain, discomfort and emotional effects may be extensive.

Market Opportunity

According to the National Psoriasis Foundation, psoriasis affects approximately 2.1% of the United States population, or more than 4.5 million people in the United States. Psoriasis also affects approximately 1% to 3% of the world's population. Approximately 150,000 to 260,000 new cases of psoriasis are diagnosed each year. In addition, each year approximately 350 people in the United States die due to complications caused by psoriasis. Primarily, such complications occur in relation to severe, extensive forms of psoriasis such as erythrodermic or pustular psoriasis, where large areas of skin are shed. Because the skin plays an important role in regulating body temperature and serving as a barrier to infection, when a person's skin is severely compromised, secondary infections may occur. These serious forms of psoriasis may also cause complicating factors, such as fluid loss and strain on the circulatory system.

The National Psoriasis Foundation also indicates that between 10% and 30%

of people who have psoriasis will also develop psoriatic arthritis, which is similar to rheumatoid arthritis, but generally milder. Psoriatic arthritis causes inflammation and stiffness in the soft tissue around joints, and frequently affects the fingers and toes. Psoriatic arthritis may also affect other areas of the body such as the wrists, neck, lower back, knees and ankles.

Psoriasis is a chronic illness that, in many cases, requires continuous treatment. Patients with psoriasis often pay for costly medications and face ongoing visits with physicians. Severe cases may require periods of hospitalization. The National Psoriasis Foundation estimates that the costs of treating psoriasis may exceed $3.0 billion annually.

Psoraxine(R)

Psoraxine(R) was developed by Dr. Jose Antonio O'Daly, our Chairman of the Board and Chief Scientific Officer. In 1991, Dr. O'Daly was conducting trials for a vaccine for leishmaniasis in Caracas, Venezuela. One patient involved in the leishmaniasis vaccine trials, who also suffered from psoriasis for 12 years, experienced complete remission of psoriasis after receiving the vaccine. As a result of this discovery, Dr. O'Daly focused his efforts on developing a product for the treatment of psoriasis. From 1992 through 2001, Dr. O'Daly developed Psoraxine(R), a purified version of the original product that is an immunotherapeutic agent presented in liquid form and

packed in 0.5 milligram ampules for intra-muscular injection. Dr. O'Daly tested the original product that was a precursor of Psoraxine(R) in approximately 2,900 patients in several clinical trials in Venezuela. The results from the studies provided evidence of remission of psoriasis lesions as a result of treatment with the product. In addition, individuals in the studies did not present severe side effects as a result of treatment. In one clinical study, of the 2,770 patients, 648, or 28%, experienced complete remission of psoriasis. In addition, almost half of the patients experienced psoriasis reduction of between 70% to 99% as measured by the Psoriasis Area and Severity Index ("PASI"). Additional studies yielded average PASI reductions of between 73% and 92%.

Dr. O'Daly licensed Psoraxine(R) to us in 2001 and moved to the United States in 2002. We made capital investments to our research and development facility of approximately $500,000 in 2002 and we filed an Investigational New Drug application with the FDA for Psoraxine(R) in March 2003. On August 4, 2003 the FDA allowed us to commence our Phase I clinical trials for Psoraxine(R).

The purpose of Phase I studies is to test the safety of a drug. We have completed our Phase I studies, which involved the administration by intramuscular injection of a single dose of 50, 150 or 300 micrograms of Psoraxine(R) or a placebo in a controlled setting to groups of psoriatic patients. Our Phase I results indicate that Psoraxine(R) is safe and well-tolerated. We spent approximately $130,000 on our Phase I studies in 2003 and approximately $210,000 on our Phase I studies in 2004.

We commenced Phase II studies in April 2004. The purpose of Phase II studies is to test the safety and efficacy of a drug. The Phase II studies have been completed. We spent approximately $2,150,000 on our Phase II studies in 2004. The initial analysis of the preliminary data from the Phase II studies indicates that treatment with Psoraxine(R) did not provide any statistically significant clinical improvement of psoriasis in participants of the studies. We are currently analyzing the data from the Phase II studies to understand why statistical significance at its primary endpoint was not achieved and to evaluate our clinical development options for Psoraxine(R). We expect that we

will be required to spend a total of approximately $4,500,000 during fiscal year 2005 to complete Phase II studies, analyze results, and redesign and implement our clinical development strategy. For the year ended December 31, 2004, we reflected $7,689,060 in research and development expenses, including $4,519,400 related to SkyePharma. For the year ended December 31, 2003, we reflected $4,045,673 in research and development expenses, including $1,721,788 related to SkyePharma.

Current Psoriasis Therapies

The topical treatment for psoriasis has been based on the use of emollients, keratolytic agents, coal tar, anthralin, corticosteroids of medium to strong potency and calcipotriene. UVB phototherapy has been used in the treatment of moderate cases of psoriasis. For severe cases, systemic treatments include methotextrate, cyclosporine and oral retinoids. Each of these treatments has variable efficacy, with side effects and cosmetic problems in addition to the failure to prevent frequent relapses.

Competition and Psoriasis Treatments in Development

The pharmaceutical and biotechnology industries are intensely competitive. Many companies, including biotechnology, chemical and pharmaceutical companies, are actively engaged in activities similar to ours, including research and development of drugs for the treatment of the same disease as Psoraxine(R). The FDA has approved Amevive, manufactured by Biogen, Raptiva, manufactured by Genentech/Xoma, and Enbrel, manufactured by Amgen and Wyeth, for the treatment

of moderate-to-severe chronic plaque psoriasis in adult patients. If we succeed in obtaining FDA approval of Psoraxine(R), Amevive, Raptiva and Enbrel may compete directly with our product. In addition to Biogen, Genentech/Xoma, Amgen and Wyeth, our competitors may include Centocor, Abbott Laboratories and Novartis. Many of these companies have substantially greater financial and other resources, larger research and development staffs, and more extensive marketing and manufacturing organizations than we have. In addition, these companies have more experience in preclinical testing, clinical trials and other regulatory approval procedures than we have. There are also academic institutions, governmental agencies and other research organizations that are conducting research in areas in which we are working. They may also come to develop and market commercial products, either on their own or through collaborative efforts.

We expect to encounter significant competition for any of the pharmaceutical products we develop. Companies that complete clinical trials obtain required regulatory approvals and commence commercial sales of their products before their competitors may achieve a significant competitive advantage.

Developments by others may render our product obsolete or noncompetitive. We will face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for establishing relationships with academic and research institutions and for licenses to additional technologies. These competitors may succeed in developing technologies or products that are more effective than Psoraxine(R).

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the

clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our potential products.

The process required by the FDA before our product candidate, Psoraxine(R), may be marketed in the United States generally involves the following:

- preclinical laboratory and animal tests;
- submission of an Investigational New Drug application, which must become effective before clinical trials may begin;
- adequate and well controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and
- FDA approval of a new drug application or biologics license application.

The testing and approval process requires substantial time, effort and financial resources, and there can be no assurance that any approvals for Psoraxine(R) or any other potential products will be granted on a timely basis, if at all.

Prior to commencing clinical trials, which are typically conducted in three sequential phases, a company must submit an Investigational New Drug application to the FDA. In March 2003, we filed our Investigational New Drug application for Psoraxine(R) with the FDA. The Investigational New Drug application automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the trial. In such a case, the Investigational New Drug sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. In August 2003, the FDA informed us that we could commence our clinical trials of Psoraxine(R). We have completed Phase I clinical trials in which Psoraxine(R) was found to be generally safe and well-tolerated in Phase I test patients. We have also recently completed a Phase II clinical trial, which did not achieve its primary endpoint for PASI (Psoriasis Area and Severity Index) reduction. We are currently analyzing the data collected during the Phase II study, including biopsy data indicating cellular level changes that has not been previously available, to gain a better understanding of the results, and to direct our future efforts.

Although we remain committed to the future clinical development of Psoraxine(R), we may not successfully complete the three phases of clinical trials of Psoraxine(R) within any specific time period, if at all. Furthermore, the FDA or an institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The results of product development, pre-clinical studies and clinical studies are submitted to the FDA as part of a new drug application or biologics license application. The FDA may deny a new drug application or biologics license application if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if such data is submitted, the FDA may ultimately decide that the new drug application or biologics license application does not satisfy the criteria for approval. Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not

maintained or if problems occur after the product reaches market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or indication. Government regulation may delay or prevent marketing of potential products or new indications for a considerable period of time and impose costly procedures upon our activities. Success in early stage clinical trials does not assure success in later stage clinical trials.

Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations which could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain, additional regulatory approvals for any of our product candidates would have a material adverse effect on our business.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with good manufacturing practices, which impose certain procedural and documentation requirements upon us and any third party manufacturers we may utilize. We cannot be certain that our present or future suppliers will be able to comply with the good manufacturing practices, regulations and other FDA regulatory requirements.

Outside the United States, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Union, registration procedures are available to companies wishing to market a product in more than one EU Member State. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization will be granted. This foreign regulatory approval process involves all of the risks associated with FDA clearance. To date, we have obtained regulatory approval for clinical testing of Psoraxine(R) in Venezuela, but we have not obtained final regulatory approval for commercial distribution of Psoraxine(R) in Venezuela because we do not have manufacturing facilities in that country and such facilities are required by regulatory authorities in Venezuela before granting commercial approval for a proposed drug.

Intellectual Property

In January 2004 the United States Patent and Trademark Office ("PTO") issued a patent to Dr. Jose O'Daly for the "Compositions and Methods for the Treatment and Clinical Remission of Psoriasis." Under the terms of a license

agreement and assignment of license agreement, we have the exclusive right and license to use and exploit this patent. Dr. O'Daly will continue to maintain ownership rights with respect to the patent and patent application. However, Dr. O'Daly has granted us a perpetual, royalty free license to his patent under the agreements, which will terminate only upon the expiration of the patent, or upon the commencement of a bankruptcy or insolvency proceeding involving our company or upon our dissolution or liquidation.

In March 2002, Akiva LLC, an entity controlled by Dr. O'Daly, also filed an application to obtain patent protection internationally under the Patent Cooperation Treaty. In addition, in August 2003, Akiva LLC filed patent applications in the European Union, Australia, Brazil, Canada, Mexico and Japan. We have rights to these applications, which are currently pending, pursuant to the license and assignment of license agreements described above.

In January 2004, Dr. O'Daly filed a patent application with the PTO focusing on the mechanism of action of Psoraxine(R), expanding the claims to include medical indications other than psoriasis, such as Atopic Dermatitis, Psoriatic Arthritis and Rheumatoid Arthritis. In addition, the patent elaborates further on the mechanism of action of Leishmania extracts, which are believed to induce T-cell activation. In January 2004, Dr. O'Daly also filed a second patent relating to a culture medium for parasitic organisms, which is part of our technology platform. Dr. O'Daly has assigned to us the rights in the patent applications. Also, in January 2004, the PTO granted us a federal trademark registration for the mark Psoraxine(R).

Agreements with SkyePharma

We entered into a Purchase Agreement dated as of December 10, 2001 with SkyePharma PLC ("SkyePharma") pursuant to which SkyePharma purchased an aggregate of 2,000,000 shares of our Series A Convertible Preferred Stock, par value $.001 per share ("Series A Preferred Stock"), for an aggregate purchase price of $20.0 million. On January 20, 2004, pursuant to our Omnibus Conversion Agreement with SkyePharma, dated January 12, 2004, SkyePharma converted all of its 2,000,000 shares of our Series A Preferred Stock into 25,000,000 shares of our common stock at a conversion price of $0.80 per share. In March 2005, SkyePharma also acquired an additional 11,160,000 shares of our common stock in a privately negotiated transaction with two private holders. As a result, SkyePharma beneficially owns 49.8% of our common stock.

On January 20, 2004, in connection with SkyePharma's conversion of the Series A Preferred Stock, we entered into a Call Option Agreement with SkyePharma, pursuant to which we received the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma at a premium to the $0.80 conversion price. In the event we exercise the call option, the exercise price will be between $1.28 and $1.52 per share, depending on the date of exercise. The call option will be exercisable by us for a period commencing upon our achievement of a certain milestone event and ending on January 20, 2007. In June 2004, we assigned the right to purchase 1,250,000 shares under the Call Option Agreement to FPP Capital Advisors as consideration for services it provided in negotiating the Omnibus Conversion Agreement. FPP Capital Advisors is controlled by Fabien Pictet, a member of our Board of Directors.

On January 20, 2004, the closing date of the conversion of SkyePharma's 2,000,000 shares of our Series A Preferred Stock, we, SkyePharma and our other original shareholders amended the Stockholders Agreement (the "Amended Agreement"), dated as of December 10, 2001. Pursuant to the Amended Agreement, our board of directors is now required to be comprised of at least seven

directors and must include at least two independent directors. Per the Amended Agreement, SkyePharma has the right to nominate one director. Michael Ashton is SkyePharma's initial and current nominated director. Until January 20, 2007, Jose Antonio O'Daly has the right to nominate one Director. The Amended Agreement will terminate upon the later of (i) the date on which SkyePharma no longer beneficially owns, in the aggregate, at least 20% of our outstanding common stock or (ii) January 20, 2007. Further, the Amended Agreement may be terminated by the mutual written consent of the parties. Pursuant to the Amended Agreement, SkyePharma is required to vote its shares of our common stock in favor of certain enumerated transactions that have been approved by our board of directors and all of our independent directors. These transactions include (i) the amendment of our certificate of incorporation solely to increase our authorized capital stock, (ii) the adoption or amendment of an employee benefit plan applicable to all employees, (iii) the issuance of additional securities for cash and (iv) the sale of all of our outstanding capital stock or all or substantially all of our assets, or our merger with another entity, provided that SkyePharma will receive the same consideration for its shares as other holders of common stock and will be able to participate in the sale or merger on the same terms as the most favorable terms available to any of our other stockholders and the total consideration for the transaction is greater than $135 million.

We also entered into two agreements concerning the formulation and development of our initial injectable product candidate, Psoraxine(R), with SkyePharma. Under the terms of the Technology Access Option Agreement, dated December 10, 2001, we paid to SkyePharma a $5.0 million technology access fee for the option to acquire a license for DepoFoam and other relevant drug delivery technologies owned by SkyePharma. Under the terms of the Technology Access Option Agreement, if we exercise our option, we must pay a royalty of 5%

of net sales of all products manufactured or sold that use or exploit the drug delivery technologies that we license from SkyePharma. In addition, if we exercise our option, SkyePharma retains the right during the term of the Technology Access Option Agreement to undertake the manufacture of all of our products that incorporate or utilize the drug delivery technologies. The option we received under the Technology Access Option Agreement expires on December 10, 2008. The Technology Access Option Agreement may be terminated by either party if (i) the other party commits any irremediable breach of the agreement, (ii) the other party commits any remediable breach and fails to remedy such breach within sixty days of service of notice of the breach, (iii) a court makes an administration order with respect to the other party or any composition in satisfaction of the debts of, or scheme of arrangement of the affairs of, the other party, or (iv) the other party becomes insolvent, has a receiver appointed over any of its assets, enters into any composition with creditors generally or has an order made or resolution passed for it to be wound up. SkyePharma has the right of first negotiation to acquire the worldwide marketing rights to Psoraxine(R). We have evaluated the technology access option fee we paid under the Technology Access Option Agreement, which we have been capitalizing as a research and development intangible asset over a seven-year period, and have determined that as of December 31, 2004, the technology access option fee exceeded its fair market value. Consequently, we recorded as additional research and development costs in 2004 a charge of $2,797,612 to reflect an impairment of this intangible asset.

In addition, we entered into a Service Agreement, dated December 10, 2001, pursuant to which SkyePharma was to provide us with development, manufacturing, pre-clinical and clinical development services in consideration of $11 million, of which $3 million was paid in 2001, with the remaining $8 million paid

primarily during 2002 for second generation Psoraxine(R). The Service Agreement terminated on December 31, 2002. We entered into an Amendment to the Service Agreement with SkyePharma, effective as of January 1, 2003, to extend the term of the Service Agreement and modify the services to be provided by SkyePharma such that SkyePharma continued to provide certain services to us through December 31, 2004, in consideration for payments made during 2002. The agreement expired on December 31, 2004.

Other Research and Development Efforts

In addition to our development of Psoraxine(R) for the treatment of psoriasis, we are researching its possible application for the treatment of other conditions, such as eczema, seborrheic dermatitis and leishmaniasis. We are also developing a second product for the treatment of arthritis. We intend to market this product primarily in the United States, although we have not named this product yet and we do not have any approvals from, nor has any application been filed with, the FDA or any foreign governmental regulatory authority for this product. Currently, we do not have any collaborators for this product. We are also engaged in preliminary research of a treatment for transplant rejection.

Employees and Consultants

As of December 31, 2004, we employed seven full-time employees, including four scientists and one laboratory technician. We also have 14 consultants. We have no part-time employees. None of our employees are covered by a collective bargaining agreement and we believe that our employee relations are good.

Forward-Looking Statements

This annual report on Form 10-KSB contains many forward-looking statements that involve substantial risks and uncertainties. You can identify these statements by forward-looking words such as "may", "will", "expect", "anticipate", "believe", "estimate", and "continue" or similar words. You should read statements that contain these words carefully because they discuss our future expectations, contain projections of our future operating results or of our financial condition or state other "forward-looking" information.

We believe that it is important to communicate our future expectations to our investors. However, we may be unable to accurately predict or control events in the future. The factors listed in the sections captioned "Risk Factors" and "Management's Discussion and Analysis or Plan of Operation", as well as any other cautionary language in this annual report, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Before you invest in our common stock, you should be aware that the occurrence of the events described in the "Risk Factors" section, the "Management's Discussion and Analysis or Plan of Operation" section and elsewhere in this annual report could seriously harm our business.

Risk Factors

We will need to obtain additional funds immediately to support our future operation expenses. Our auditors have expressed uncertainty regarding our

ability to continue as a going concern.

Based on our current plans, we believe that we have sufficient funds to meet our operating expenses and capital requirements through approximately the 2nd quarter of 2005. We will need to raise additional funds to continue our operations following that period. Furthermore, substantial additional funds will be needed in order to fund our continued efforts to obtain FDA approval of Psoraxine(R), especially given the failure of our Phase II study to meet its primary endpoint. No assurance can be given that we will be able to obtain financing, or successfully sell assets or stock, or, even if such transactions are possible, that they will be on terms reasonable to us or that they will enable us to satisfy our cash requirements. In addition, raising additional funds by selling additional shares of our capital stock will dilute the ownership interest of our stockholders. If we do not obtain additional funds, we will likely be required to eliminate programs, delay development of our products, alter our business plans, or in the extreme situation, cease operations.

As a result of our losses and the matters described in the preceding paragraph, the Independent Auditors' Report on our financial statements includes a paragraph indicating doubt about our ability to continue as a going concern. The financial statements that accompany this report do not include any adjustments that might be necessary if we are unable to continue as a going concern.

We have no sales; we will not have sales in the foreseeable future; we are in an early stage of development and we may never sell products or become profitable.

We commenced our current operations in 2001 and such operations remain in an early stage of development. We have no products approved for sale and therefore, no means to generate revenue. We have not commercialized any products, had no revenues and had incurred a cumulative net loss of $49,702,357 as of December 31, 2004 which has increased to date. The cumulative net loss through December 31, 2004 includes non-cash preferred stock dividends of $22,218,750. We expect that substantial losses will continue for the foreseeable future. In order to obtain revenue from the sales of our product candidate, Psoraxine(R), we must successfully develop, test, obtain regulatory approval for, manufacture, market and eventually sell such product candidate. Our expenses have consisted principally of costs incurred in research and development and from general and administrative costs associated with our operations. We expect our expenses to increase and to continue to incur operating losses for the next several years as we continue our research and development efforts for Psoraxine(R) and any subsequent product candidates. Commercialization of any of our products will take a significant amount of time and successful commercialization may not occur at all. As a result, we may never become profitable.

Psoraxine(R) may never be approved by the FDA because the results of our Phase II study failed to meet its primary study endpoint.

We have focused our development efforts to date on conducting clinical trials for an immuno-stimulatory drug, Psoraxine(R), for the treatment of psoriasis. We recently conducted a randomized, double-blinded, placebo-controlled clinical study involving 120 patients with moderate to severe psoriasis who received six (6) intramuscular injections of Psoraxine(R). The primary endpoint of the study was a specified level of improvement of symptoms measured in accordance with the Psoriasis Area and Severity Index, or PASI, which is a measurement scale that ranks the severity of symptoms of patients suffering from psoriasis. Our initial analysis of the preliminary data showed no statistically significant improvement of those Phase II study patients who received six injections of Psoraxine(R) for a twelve weeks treatment period

compared to patients taking a placebo.

The failure of our Phase II study to meet its primary endpoint makes FDA approval of Psoraxine(R) substantially more uncertain. To continue Psoraxine(R)'s development and to obtain FDA approval to market Psoraxine(R), we must analyze the data from the Phase II study to identify why the Phase II study failed to meet its primary endpoint. We must then undertake additional Phase I or Phase II clinical trials that are adjusted to account for the cause or causes of the initial Phase II study's failure. Although we have already identified a number of possible reasons for the failure to demonstrate efficacy in the recent Phase II trial, and we have also developed a preliminary plan for new clinical studies, there can be no guarantee that we will be able to identify with certainty why our Phase II study failed to meet its primary endpoint and that we will be able to make the needed adjustments for further Phase II studies to be successful. There is also no guarantee that the FDA would approve Psoraxine(R) even if we deem additional clinical trials to be successful.

We have devoted most of our resources to the development of Psoraxine(R) and our business is dependent on its success. In the United States, the marketing of Psoraxine(R) depends on FDA approval of the product. Analyzing the Phase II study data and conducting additional Phase II clinical trials will delay FDA approval. We may also decide to discontinue further clinical trials of Psoraxine(R), which would prevent us from obtaining FDA approval. If we are not able to obtain FDA approval for Psoraxine(R), we would be unable to sell the product and we would have to identify new potential products to develop.

Recent and future changes in senior management may affect our ability to implement our business plan.

On July 28, 2004, we accepted the resignations of Mike Ajnsztajn and Gina Tedesco, effective immediately with respect to their positions as members of our Board of Directors and effective as of August 26, 2004 with respect to their positions as our Chief Executive Officer and Chief Financial Officer, respectively. On October 13, 2004, we retained Peter Golikov as interim Chief Executive Officer and Michael Garone as interim Chief Financial Officer. On November 24, 2004, Mr. Golikov ceased being our interim Chief Executive Officer.

On February 15, 2005, we retained James Sharpe as our Chief Executive Officer. On February 21, 2005, we retained Michael Garone as our Chief Financial Officer. Our ability to implement our business strategy may be adversely affected if we continue to experience unplanned senior management changes in the future or if we are unable to successfully integrate our current and future senior management personnel into our organization.

One of our existing stockholders can exert control over us and may not make decisions that further the best interests of all stockholders.

SkyePharma acquired 11,160,000 additional shares of our common stock on March 3, 2005, in a privately negotiated transaction, increasing its ownership of our common stock from 34.5% to 49.8%. As a result, SkyePharma may exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. Furthermore, the interests of SkyePharma may not always coincide with our interests or the interests of other

stockholders and accordingly, they could cause us to enter into transactions or agreements which we would not otherwise consider. In addition, this concentration of ownership may delay or prevent a merger or acquisition resulting in a change in control of us and might affect the market price of our common stock, even when such a change in control may be in the best interest of all stockholders.

We may not be successful in the development and commercialization of products.

We may not develop products that prove to be safe and effective, that meet applicable regulatory standards or that we can manufacture at reasonable costs or market successfully. Successful products will require significant development and investment, including testing, to demonstrate their safety and efficacy prior to their commercialization. We have not proven our ability to develop and commercialize products. We must conduct a substantial amount of additional research and development before any regulatory authority will approve our initial product candidate, Psoraxine(R). Our research and development and clinical trials may not confirm the safety and efficacy of our products, in which case regulatory authorities may not approve them. In addition, even if we successfully complete our research and development efforts, Psoraxine(R) may not perform in the manner we anticipate, and may not be accepted for use by the public.

Substantial additional funds and effort will be necessary for further development and commercialization of Psoraxine(R).

Our initial product candidate, Psoraxine(R), will require the commitment of substantial resources to move it towards commercialization. Before obtaining regulatory approvals for the commercial sale of Psoraxine(R), we must demonstrate the safety and efficacy of our product candidate through preclinical testing and clinical trials. Conducting clinical trials involves a lengthy, expensive and uncertain process. Completion of clinical trials may take several years or more. The length of time generally varies substantially according to the type, complexity, novelty and intended use of the product. If we or the U.S. Food and Drug Administration believe that our clinical trials expose participating patients to unacceptable health risks, we may suspend such trials. We may encounter problems in our studies which will cause us or the FDA to delay or suspend the studies. Some of the factors that may delay our commencement and rate of completion of clinical trials include:

- ineffectiveness of the study compound, or perceptions by physicians that the compound will not successfully treat a particular indication;
- inability to manufacture sufficient quantities of compounds for use in clinical trials;
- failure of the FDA to approve our clinical trial protocols;
- slower than expected rate of patient recruitment;
- unforeseen safety issues; or
- government or regulatory delays.

The failure of future clinical trials may harm our business, financial condition and results of operations.

Our potential therapeutic products face a lengthy and uncertain regulatory process. If we do not obtain regulatory approval of our potential products, we will not be able to commercialize these products.

The FDA must approve any therapeutic product before it can be marketed in the United States. Before we obtain FDA approval of a new drug application or biologics license application, the product must undergo extensive testing, including animal and human clinical trials, which can take many years and requires substantial expenditure. Data obtained from such testing may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. In addition, changes in regulatory policy for product approval during the period of product development and regulatory agency review of each submitted new drug application may cause delays or rejections. We must devote a substantial amount of time and resources in the regulatory process in order to obtain regulatory approval of our initial product candidate, Psoraxine(R).

Because our initial product candidate, Psoraxine(R), involves the application of new technologies and may be used upon new therapeutic approaches, government regulatory authorities may subject this product to more rigorous review and may grant regulatory approvals more slowly for this product than for products using more conventional technologies. We have not received approval from the FDA to market or commercialize Psoraxine(R). The regulatory agencies of foreign governments must also approve any therapeutic product we may develop before the product can be sold in those countries. To date, although we have obtained regulatory approval for clinical testing of Psoraxine(R) in Venezuela, we have not sought, nor have we obtained, regulatory approval for the commercialization of Psoraxine(R) in Venezuela because, among other things, we do not have manufacturing facilities in that country and such facilities are required by regulatory authorities in Venezuela before granting commercial approval for a proposed drug.

Even after investing significant time and resources, we may not obtain regulatory approval for our product. If we do not receive regulatory approval, we cannot sell the product. Even if we receive regulatory approval, this approval may place limitations on the indicated uses for which we can market the product. Further, after granting regulatory approval, regulatory authorities subject a marketed product and its manufacturer to continual review, and discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer and manufacturing facility, including withdrawal of the product from the market. In certain countries, regulatory agencies also set or approve prices.

Even if product candidates emerge successfully from clinical trials, we may not be able to successfully manufacture, market and sell them.

We have not successfully completed clinical trials of Psoraxine(R). If Psoraxine(R) emerges successfully from clinical trials and obtains regulatory approval, we will either commercialize products resulting from our proprietary programs directly or through licensing arrangements with other companies. We have no experience in manufacturing and marketing, and we currently do not have the resources or capability to manufacture, market or sell our products on a commercial scale. In order to commercialize Psoraxine(R) directly, we would need to develop or obtain through outsourcing arrangements the capability to manufacture, market and sell products. In addition, we currently do not have any agreements for the marketing or sale of any of our products and we may not be able to enter into such agreements on commercially reasonable terms, or at all.

We license and do not own our intellectual property. any inability to protect our proprietary technologies adequately could harm our competitive position.

We license, and do not own, the intellectual property rights to Psoraxine(R). Dr. Jose Antonio O'Daly is the owner of the patent for Psoraxine(R). Under the terms of a license agreement and assignment of license agreement, we have the right to use any patent issued pursuant to Dr. O'Daly's patent application. We also have rights to other patents filed by Dr. O'Daly under the terms of our employment agreement with him. Our success will depend in part on our ability to obtain patents and maintain adequate protection of other intellectual property for our technologies and products in the United States and other countries. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate our competitive advantage. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these foreign countries.

The patent positions of biotechnology companies, including our patent positions, involve complex legal and factual questions and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated or circumvented. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that we cover our proprietary technologies with valid and enforceable patents or we effectively maintain such proprietary technologies as trade secrets. We will apply for patents covering both our technologies and product candidates as we deem appropriate. However, we may fail to apply for patents on important technologies or products in a timely fashion, or at all, and in any event, the applications we do file may be challenged and may not result in issued patents. Any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patented technologies. In addition, others may challenge or invalidate our patents, or our patents may fail to provide us with any competitive advantages. If we encounter challenges to the use or validity of any of our patents, resulting in litigation or administrative proceedings, we would incur substantial costs and the diversion of management in defending the patent. In addition, we do not control the patent prosecution of technology that we license from others. Accordingly, we cannot exercise the same degree of control over this intellectual property as we would over technology we own.

We rely upon trade secrets protection for our confidential and proprietary information. We have taken measures to protect our proprietary information. These measures may not provide adequate protection for our trade secrets or other proprietary information. We seek to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants. Nevertheless, employees, collaborators or consultants may still disclose our proprietary information, and we may not be able to meaningfully protect our trade secrets. In addition, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our trade secrets.

Many potential competitors which have greater resources and experience than we do may develop products and technologies that could make ours obsolete.

Companies in the biotechnology industry face rapid technological change in a rapidly evolving field. Our future success will depend on our ability to maintain a competitive position with respect to technological advances. Rapid technological development by others may result in our products and technologies becoming obsolete.

We face, and will continue to face, intense competition from organizations such as large biotechnology and pharmaceutical companies, as well as academic and research institutions and government agencies. Our competitors may include Biogen, Genentech/Xoma, Amgen, Wyeth, Abbott Laboratories and Novartis. These organizations may develop technologies that provide superior alternatives to our technologies. Further, our competitors may be more effective at implementing their technologies to develop commercial products.

Any products that we develop through our technologies will compete in multiple, highly competitive markets. Many of the organizations competing with us in the markets for such products have greater capital resources, research and development and marketing staffs, facilities and capabilities, and greater

experience in obtaining regulatory approvals, product manufacturing and marketing. Accordingly, our competitors may be able to develop technologies and products more easily, which would render our technologies and products obsolete and noncompetitive.

If we lose our key personnel or fail to attract and retain additional personnel, we may be unable to discover and develop our products.

We depend on the services of Dr. Jose Antonio O'Daly, the Chairman of our Board of Directors and our Chief Scientific Officer, the loss of whose services would adversely impact the achievement of our objectives. We recently hired a Chief Executive Officer and Chief Financial Officer. To execute our business plan fully it is essential that we retain these executives. In addition, recruiting and retaining qualified scientific personnel to perform future research and development work will be critical to our success. Although we believe we can successfully attract and retain qualified personnel, we face intense competition for experienced scientists. Failure to attract and retain skilled personnel would prevent us from pursuing collaborations and developing our products and core technologies to the extent otherwise possible.

Our planned activities will require additional expertise. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing management personnel. The inability to acquire or develop this expertise could impair the growth, if any, of our business.

If we face claims in clinical trials of a drug candidate, these claims will divert our management's time and we will incur litigation costs.

We face an inherent business risk of clinical trial liability claims in the event that the use or misuse of Psoraxine(R) results in personal injury or death. We may experience clinical trial liability claims if our drug candidates are misused or cause harm before regulatory authorities approve them for marketing. Although, we currently maintain clinical liability insurance coverage, it may not sufficiently cover any claims made against us and may not be available in the future on acceptable terms, if at all. Any claims against us, regardless of their merit, could strain our financial resources in addition to consuming the time and attention of our management. Law suits for any injuries caused by our products may result in liabilities that exceed our total assets.

The market price of our common stock may be highly volatile.

The market price of our common stock has been and will likely continue to be highly volatile. From the date trading of our common stock commenced until March 29, 2005, the range of our stock price has been between $.16 and $7.15. Factors including announcements of technological innovations by us or other companies, regulatory matters, new or existing products or procedures, concerns about our financial position, operating results, government regulation, or developments or disputes relating to agreements, patents or proprietary rights may have a significant impact on the market price of our stock. In addition, potential dilutive effects of future sales of shares of common stock by us, our stockholders, or the holders of warrants and options, could have an adverse effect on the price of our common stock.

A large number of shares of our common stock may be sold in the market, which may depress the market price of our common stock.

Sales of substantial amounts of our common stock in the public market, or the perception that these sales might occur, could materially and adversely affect the market price of our common stock or our future ability to raise capital through an offering of our equity securities. We have an aggregate of 73,173,055 shares of our common stock outstanding. If all options and warrants currently outstanding to purchase shares of our common stock are exercised, there will be approximately 90,120,946 shares of common stock outstanding. Of the outstanding shares, up to 73,148,055 shares are freely tradable without restriction or further registration under the Securities Act, unless the shares are held by one of our "affiliates" as such term is defined in Rule 144 of the Securities Act. The remaining shares may be sold only pursuant to a registration statement under the Securities Act or an exemption from the registration requirements of the Securities Act. The sale and distribution of these shares may cause a decline in the market price of our common stock.

Our common stock qualifies as a "penny stock" under SEC rules which may make it more difficult for our stockholders to resell their shares of our common stock.

Our common stock trades on the OTC Bulletin Board. As a result, the holders of our common stock may find it more difficult to obtain accurate quotations concerning the market value of the stock. Stockholders also may experience greater difficulties in attempting to sell the stock than if it were listed on a stock exchange or quoted on the Nasdaq National Market or the Nasdaq Small-Cap Market. Because our common stock does not trade on a stock exchange or on the Nasdaq National Market or the Nasdaq Small-Cap Market, and the market price of the common stock is less than $5.00 per share, the common stock qualifies as a "penny stock." SEC Rule 15g-9 under the Securities Exchange Act of 1934 imposes additional sales practice requirements on broker-dealers that recommend the purchase or sale of penny stocks to persons other than those who qualify as an "established customer" or an "accredited investor." This includes the requirement that a broker-dealer must make a determination on the appropriateness of investments in penny stocks for the customer and must make special disclosures to the customer concerning the risks of penny stocks. Application of the penny stock rules to our common stock could adversely affect the market liquidity of the shares, which in turn may affect the ability of holders of our common stock to resell the stock.

Item 2. Description of Property

We lease our executive offices and research laboratory located at 75

Passaic Avenue, Fairfield, New Jersey 07004. The yearly rent for such office and laboratory space is $77,500.

Item 3. Legal Proceedings

Neither we, nor any of our properties, are presently a party to any material legal proceeding, nor, to our knowledge, is any such proceeding threatened against us or any of our properties.

Item 4. Submission of Matters to a Vote of Security Holders.

No matters were submitted for a vote of our shareholders during the fourth quarter of fiscal 2004.

PART II

Item 5. Market For Common Equity, Related Stockholder Matters and Small Business Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on the Over-the-Counter Bulletin Board ("OTC Bulletin Board") under the symbol ASTR. The following table sets forth, for the periods indicated, the range of high and low bid quotations for shares of our common stock as quoted on the OTC Bulletin Board. The reported bid quotations reflect inter-dealer prices, without retail markup, markdown or commissions, and may not necessarily represent actual transactions.

2003	High	Low
First Quarter	$0.72	$0.34
Second Quarter	$1.01	$0.40
Third Quarter	$1.41	$0.36
Fourth Quarter	$0.87	$0.42
2004		
First Quarter	$1.66	$0.64
Second Quarter	$1.46	$1.04
Third Quarter	$1.05	$0.51
Fourth Quarter	$0.85	$0.42

Holders of Common Stock

As of March 29, 2005, there were approximately 2,894 holders of our common stock.

Dividends

We have never paid or declared a cash dividend on our common stock. We intend, for the foreseeable future, to retain all future earnings for use in our business. The amount of dividends we pay in the future, if any, will be at the discretion of our Board of Directors and will depend upon our earnings, capital requirements, financial condition and other relevant factors.

Equity Compensation Plan Information

The following table provides information with respect to the equity securities that are authorized for issuance under our compensation plans as of December 31, 2004:

EQUITY COMPENSATION PLAN INFORMATION			
	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of remaining issuance u compensati (excluding reflected
Equity compensation plans approved by security holders	1,118,000	$0.45-$2.74	3,
Equity compensation plans not approved by security holders	--	--	
Total	1,118,000	$0.45-$2.74	3,

Recent Sales of Unregistered Securities

On February 15, 2005, we entered into an Employment with James Sharpe, our President and Chief Executive Officer, and a member of Board of Directors. Pursuant to the terms of the Employment Agreement, we granted Mr. Sharpe options to purchase 728,000 shares of our common stock, which will vest to the extent of 182,000 immediately and then an additional 182,000 shares per year on a cumulative basis until all options have vested. The options have an initial exercise price of $0.70 per share and have a term of ten years. In addition, Mr. Sharpe was issued 100,000 shares of our common stock, which were fully vested and considered fully paid when issued. On February 15, 2006, Mr. Sharpe will be issued an additional 100,000 shares of our common stock, which will be fully vested and fully paid on the date of issuance.

On December 10, 2004, we entered into an Employment Agreement with Jose Antonio O'Daly, the Chairman of our Board of Directors and our Chief Scientific Officer. Pursuant to the terms of the Employment Agreement, we granted Dr. O'Daly options to purchase 728,000 shares of our common stock at an initial exercise price of $0.70 per share. The options were fully vested upon grant and expire in ten years.

On July 9, 2004, Steven Fulda, a member of our Board of Directors, exercised options to purchase 25,000 shares of our common stock at $0.45 per share.

On July 2, 2004, we granted options to purchase 50,000 shares of our common stock at an exercise price of $1.00 per share to Samuel Barnett, one of our Directors. Twenty-five percent of the options were vested upon the date of

grant, and options to purchase an additional 12,500 shares of our common stock will vest each year thereafter on the anniversary of the date of grant. The options will expire in four years.

In June 2004, we issued units consisting of 150,000 shares of common stock and warrants to purchase 150,000 shares of common stock to FPP Capital Advisors, which is controlled by Fabien Pictet, a member of our Board of Directors, in consideration for services valued at $75,000 that were rendered to us in negotiating a Call Option Agreement, dated January 12, 2004, between us and SkyePharma. The 150,000 warrants have an exercise price of $0.73 per share of common stock and expire five years from the date of issue. Under the Call Option Agreement, SkyePharma agreed that up to 12,500,000 shares of its common stock issued upon conversion of the Series A Convertible Preferred Stock will be subject to a call option, exercisable at our discretion upon completion of agreed upon milestones and ending on January 20, 2007. In the event we exercise the call option, the exercise price will be between $1.28 and $1.52 per share, depending on the date of exercise. We assigned to FPP Capital Advisors the right to purchase 1,250,000 shares of our common stock pursuant to the Call Option Agreement. We relied on the exemption from registration with the Securities and Exchange Commission provided under Section 4(2) of the Securities Act of 1933 and Rule 506 of Regulation D under the Securities Act of 1933.

On January 20, 2004 and February 19, 2004, we sold to accredited investors units consisting of an aggregate of 10,459,866 shares of common stock and warrants to purchase 10,459,866 shares of common stock for an aggregate purchase price of approximately $5.23 million. The warrants have an exercise price of $0.73 and expire in four years. We relied on the exemption from registration under Regulation D of the Securities Act of 1933. In July 2004, we filed a registration statement under the Securities Act of 1933 covering the resale of the shares purchased and the shares issuable upon exercise of the warrants.

In connection with the private placements on January 20, 2004 and February 19, 2004, FPP Capital Advisors received a consulting fee of $261,496, warrants to purchase 418,394 shares of our common stock at $0.50 per share and warrants to purchase 418,394 shares of our common stock at $0.73 per share. The warrants expire in four years. FPP Capital Advisors will be paid an additional consulting fee equal to 5% of the proceeds we receive upon exercise of the warrants issued in the private placements. We relied on the exemption from registration with the Securities and Exchange Commission provided under Section 4(2) of the Securities Act of 1933 and Rule 506 of Regulation D under the Securities Act of 1933.

On January 20, 2004, pursuant to an Omnibus Conversion Agreement, dated January 12, 2004, between us and SkyePharma, SkyePharma converted all of its 2,000,000 outstanding shares of Series A Convertible Preferred Stock into 25,000,000 shares of our common stock at a conversion price of $0.80 per share. As a result of this conversion, we no longer have any shares of preferred stock outstanding and SkyePharma no longer has rights as a preferred stockholder. We relied on the exemption from registration with the Securities and Exchange Commission provided under 4(2) of the Securities Act of 1933 and Rule 506 of Regulation D under the Securities Act of 1933.

During the thirteen month period ending January 31, 2003, SkyePharma purchased 2,000,000 shares of our Series A Convertible Preferred Stock, par value $.001 per share pursuant to a Purchase Agreement dated as of December 10, 2001, at a purchase price of $10.00 per share, or an aggregate purchase price of $20.0 million. We sold these shares in reliance on the exemption from registration with the Securities and Exchange Commission provided under Section 4(2) and Rule 506 of Regulation D under the Securities Act of 1933.

On January 10, 2002, Mike Ajnsztajn, our former Chief Executive Officer and a former member of our Board of Directors, Jose Antonio O'Daly, the Chairman of our Board of Directors and our Chief Scientific Officer, and Gaston Liebhaber, a former member of our Board of Directors, transferred, respectively, 175,000, 275,000 and 50,000 shares of our common stock owned by them to Manuel Tarabay for consulting services rendered by Mr. Tarabay in connection with their efforts to raise capital for our company. Messrs. Ajnsztajn, O'Daly and Liebhaber relied on the exemption from registration afforded by Section 4(2) of the Securities Act of 1933.

Item 6. Management's Discussion and Analysis or Plan of Operation

The following discussion of our financial condition and plan of operation should be read in conjunction with our financial statements and the related notes included elsewhere in this annual report on Form 10-KSB. This annual report contains certain statements of a forward-looking nature relating to future events or our future financial performance. We caution prospective investors that such statements involve risks and uncertainties, and that actual events or results may differ materially. In evaluating such statements, prospective investors should specifically consider the various factors identified in this annual report, including the matters set forth under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We disclaim any obligation to update information contained in any forward-looking statement.

Overview

We are a development stage biotechnology company engaged primarily in the research and development of treatments for immune system disorders and skin diseases. Our initial product candidate, Psoraxine(R), is a protein extract used for the treatment of the skin disease psoriasis.

Currently, we are engaged in the following activities to further our development efforts of our initial product candidate:

- Ongoing research and development of Psoraxine(R);
- Conducting clinical trials to obtain the approval of the United States Food and Drug Administration for the marketing of Psoraxine(R); and

- Development of the technology underlying Psoraxine(R) for the treatment of indications other that psoriasis, such as eczema, seborrheic dermatitis and leishmaniasis.

Fiscal year ended December 31, 2004 compared to fiscal year ended December 31, 2003

For fiscal year ended December 31, 2004:

On January 20, 2004 we closed a private placement from which we received gross proceeds of approximately $4.08 million. The transaction consisted of the sale to accredited investors of units consisting of 8,159,964 shares of common stock and warrants to purchase 8,159,964 shares of common stock. Concurrently with this transaction, SkyePharma converted all of its outstanding shares of Series A Preferred Stock into 25,000,000 shares of common stock at a reduced conversion price of $0.80 per share. In accordance with Statement of Financial Auditing Standard 84, "Induced Conversions of Convertible Debt, an Amendment of

APB Opinion No. 26," we recorded this conversion transaction as a non-cash preferred stock dividend in January 2004 in the amount of $10,750,000.

On February 19, 2004, we held a second closing for our private placement from which we received gross proceeds of approximately $1.15 million. The transaction consisted of the sale to accredited investors of units consisting of 2,299,902 shares of common stock and warrants to purchase 2,299,902 shares of common stock. In connection with our private placements and the conversion of SkyePharma's Series A Preferred Stock, SkyePharma agreed that 12,500,000 shares of the common stock issued upon conversion will be subject to a right of repurchase by us under certain circumstances at a premium to the conversion price. We assigned the right to purchase 1,250,000 of these shares to FPP Capital Advisors as consideration for services it provided to us in negotiating the Series A Preferred Stock conversion by SkyePharma. Accordingly, we recorded a non-cash charge of $376,508 in June 2004 in connection with this assignment.

In February 2004, in connection with the private placement, FPP Capital Advisors received a consulting fee of $261,496, warrants to purchase 418,394 shares of our common stock at $0.50 per share and warrants to purchase 418,394 shares of our common stock. In June 2004, we issued units consisting of 150,000 shares of common stock and warrants to purchase 150,000 shares of common stock to FPP Capital Advisors in consideration for services rendered to us in negotiating our right to repurchase 12,500,000 shares of common stock from SkyePharma.

For the fiscal year ended December 31, 2004, we had no revenue from operations and incurred operating expenses of $9,580,307 which consisted primarily of:

- Research and development costs of $7,689,060, including $2,360,000 that we incurred to conduct our Phase I and Phase II clinical studies, $1,007,500 for services provided by SkyePharma under our Service Agreement with them, amortization of approximately $714,288 of the technology option license under our Technology Access Option Agreement with SkyePharma as an intangible asset over its seven-year life, and a charge of $2,797,612 to record an impairment of the technology option license.

- General and administrative costs of approximately $1,860,844, including professional fees and our general corporate expenditures.

1 As a result, during the fiscal year ended December 31, 2004, we incurred a net loss of $20,037,568, which also included a non-cash preferred stock dividend of $10,750,000.

In December 2004, we received $293,461 in cash from the sale of a portion of our tax related net operating losses ("NOLS") under the State of New Jersey's Technology Business Tax Certificate Transfer Program. The program is an initiative adopted by the New Jersey State legislature that allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of NOLS and defined research and development tax credits for cash.

For fiscal year ended December 31, 2003:

In January 2003, pursuant to a Purchase Agreement dated as of December 10, 2001, we sold 250,000 shares of our Series A Convertible Preferred Stock to SkyePharma for an aggregate purchase price of $2,500,000. We received proceeds of $2,480,000 after we netted out from the proceeds $20,000 due to SkyePharma in

connection with the Service Agreement.

During the fiscal year ended December 31, 2003, we received $825,000 outstanding under subscription notes. In April 2003, we entered into an Amended Investor Relation Agreement with a stockholder who had outstanding subscription notes. In exchange for services rendered, we reduced the outstanding amount by $36,000. In 2004, the stockholder will provide services valued at $24,000 in lieu of payment of the outstanding subscription receivable balance.

For the fiscal year ended December 31, 2003, we had no revenue from operations and incurred operating expenses of $5,362,081 which consisted primarily of:

- Research and development costs of $4,045,673, including $1,007,500 that we incurred in connection with services provided by SkyePharma under our Service Agreement with them and amortization of approximately $714,288 under our technology option license which is being amortized over a seven year period.

- General and administrative costs of approximately $1,290,346, including professional fees and our general corporate expenditures.

As a result, during the fiscal year ended December 31, 2003, we incurred a net loss of $5,080,427.

In December 2003, we received $221,636 in cash from the sale of a portion of our tax related net operating losses ("NOLS") under the State of New Jersey's Technology Business Tax Certificate Transfer Program. The program is an initiative adopted by the New Jersey State legislature that allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of NOLS and defined research and development tax credits for cash.

The Next Twelve Months

At December 31, 2004 we had cash balances of $2,312,401, which we estimate will last us through approximately the second quarter of 2005, and no marketable securities.

Based on our current operating plan, we anticipate conducting the following activities and using our cash over the course of the next twelve months as follows:

- Our primary focus is to further our development efforts of our initial product candidate, Psoraxine(R). In March 2005, the Company announced that the Phase II study of its novel immuno-stimulatory product for the treatment of Psoriasis did not meet the primary study endpoint upon completion of the treatment phase of the study. In the study, Psoraxine(R) was found to be safe and well-tolerated. Accordingly, we are currently analyzing the data to understand why we received these unexpected results. In this regard, we are implementing cost containment measures and realigning development activities to focus on such things as formulation, manufacturing, analytical protocols and potency. We remain committed to Psoraxine(R) and its future development, and hope to see it return to Phase II clinical trials in 2006. We also remain committed to exploring applications of our technology platform in other dermatological diseases, as well as in other therapeutic areas including arthritis. We expect that we would be required to incur

expenses of approximately $2,500,000 to third parties in connection with continuing development of Psoraxine(R) and exploration of other applications of the technology.

- We intend to implement our business plan and facilitate the operations of our company. We will spend approximately $1,250,000 to pay management salaries and salaries of employees, a portion of which is treated as research and development expense.

- We also expect to expend approximately $1,100,000 for our general administrative and working capital requirements.

We will need to raise additional funds immediately to continue our operations for the period following the second quarter of 2005 and to fund any of the activities described above. Furthermore, substantial additional funds will be needed in order to fund our continued efforts to obtain FDA approval of Psoraxine(R). No assurance can be given that we will be able to obtain financing on terms that we find acceptable, or that they will enable us to satisfy our cash requirements. In addition, raising additional funds by selling additional shares of our capital stock will dilute the ownership interest of our stockholders. If we do not obtain additional funds, we will likely be required to eliminate programs, delay development of our products, or in the extreme situation, cease operations.

Item 7. Financial Statements

The financial statements required by this Item 7 begin at page F-1 of this annual report.

Item 8. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 8A. Controls and Procedures

(a) Evaluation of disclosure controls and procedures.

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-KSB, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

(b) Changes in internal controls.

There were no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Item 8B. Other Information

None.

PART III

Item 9. Directors and Executive Officers of the Registrant; Compliance With Section 16(a) of the Exchange Act.

We have a Code of Business Conduct and Ethics that applies to all directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. You can find our Code of Business and Ethics on our website by going to the following address: www.astralisltd.com. We will post any amendments to the Business Code of Conduct and Ethics as well as any waivers that are required to be disclosed by the rules of the Securities and Exchange Commission on our website.

Our Board of Directors has adopted Corporate Governance Guidelines and Charters for the Audit, Compensation and Nominating and Corporate Governance Committees of the Board of Directors. You can find these documents on our website by going to the following address: www.astralisltd.com.

You can also obtain a printed copy of any of the materials referred to above by contacting us at the following address: 75 Passaic Avenue, Fairfield, New Jersey 07004, Attention: Secretary. Telephone number (973) 227-7168.

The Audit Committee of our Board of Directors is an "Audit Committee" for the purposes of Section 3(a)(58) of the Securities Exchange Act of 1934. The members of that Committee are Steven Fulda and Samuel Barnett.

Apart from certain information concerning our Executive Officers which is set forth in Part I of this Report, the other information required by this item is incorporated herein by reference to the applicable information in the proxy statement for our 2005 Annual Meeting including the information set forth under the captions "Election of Directors, Section 16(a) Beneficial Ownership Reporting Compliance and Governance of the Company - Audit Committee."

Item 10. Executive Compensation.

The information concerning our executive compensation required by Item 10 shall be included in the Proxy Statement to be filed relating to our 2005 Annual Meeting of Stockholders and is incorporated herein by reference, including the information set forth under the caption "Executive Compensation."

Item 11. Security Ownership of Certain Beneficial Owners and Management

The information concerning our beneficial owners required by Item 11 shall be included in the Proxy Statement to be filed relating to our 2005 Annual Meeting of Stockholders and is incorporated herein by reference, including the information set forth under the caption "Share Ownership of Certain Beneficial Owners, Directors and Officers."

Item 12. Certain Relationships and Related Transactions.

The information concerning certain relationships and related transactions required by Item 12 shall be included in the Proxy Statement to be filed relating to our 2005 Annual Meeting of Stockholders and is incorporated herein by reference, including the information set forth under the caption "Certain Relationships and Related Transactions."

Item 13. Exhibits and Reports on Form 8-K.

(a) Exhibits

Exhibit Number	Description
3.1 *	Certificate of Incorporation of Astralis Ltd.
3.2 *	Amendment to the Certificate of Incorporation of Astralis Ltd.
3.3	Bylaws of Astralis Ltd.
3.4	Amendment to the Bylaws of Astralis Ltd.
4.1 **	Specimen of Stock Certificate for Common Stock of Astralis Ltd.
10.1 ***	Agreement and Plan of Merger, dated November 21, 2001
10.2 #	Contribution Agreement, dated as of September 10, 2001, between Astralis Ltd., Astralis LLC and the members of Astralis LLC
10.3 ##	Purchase Agreement, dated December 10, 2001, between Astralis Ltd. and SkyePharma PLC
10.4 ##	Stockholder Agreement, dated December 10, 2001, between Astralis Ltd., SkyePharma PLC, Jose Antonio O'Daly, Mike Ajnsztajn and Gaston Liebhaber
10.5 ###	2001 Stock Option Plan
10.6 +	Sub-Lease Agreement, dated February 2002, between SGS U.S. Testing Company Inc. and Astralis Ltd.
10.7 +	License Agreement dated April 26, 2001 between Jose Antonio O'Daly and Astralis LLC
10.8 +	Assignment of License, dated November 13, 2001, between Astralis LLC and Astralis Ltd. (f/k/a Hercules Development Group, Inc.)
10.9 +	Form of Warrant
10.10 ++	Agreement for Services dated December 10, 2001 between SkyePharma Inc. and Astralis Ltd.
10.11 ++	Technology Access Option Agreement dated December 10, 2001 by and among SkyePharma Inc., SkyePharma Holding AG and Astralis Ltd.
10.12 +++	Employment Agreement dated December 10, 2001, between Dr. Jose Antonio O'Daly and Astralis Ltd.
10.13 +++	Amendment #1 to Agreement for Services dated March 18, 2003 between SkyePharma Inc. and Astralis Ltd.

10.14 *	Omnibus Conversion Agreement dated January 12, 2004 between Astralis Ltd. and SkyePharma PLC
10.15 *	Call Option Agreement dated January 20, 2004 between Astralis Ltd. and SkyePharma PLC
10.16 *	Amendment No. 1, dated January 20, 2004, to Stockholders Agreement, dated December 10, 2001 by and among Astralis Ltd., SkyePharma PLC, Jose Antonio O'Daly, Mike Ajnsztajn, Gaston Liebhaber and Gina Tedesco
10.17	Employment Agreement dated December 22, 2004 between Astralis Ltd. and Jose Antonio O'Daly
10.18	Employment Agreement dated January 27, 2005 between Astralis Ltd. and James Sharpe
10.19	Consultant Agreement dated February 21, 2005 between Astralis Ltd. and Michael Garone
14.1 *	Code of Ethics for CEO and Senior Financial Officers
31.1	Certification by the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification by the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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* Previously filed with the Securities and Exchange Commission as an Exhibit to the Annual Report on Form 10-KSB on March 30, 2004.

** Previously filed with the Securities and Exchange Commission as an Exhibit to the Registration Statement on Form SB-2 for Astralis Ltd. on May 28, 2004.

*** Previously filed with the Securities and Exchange Commission as an Exhibit to the Preliminary Proxy Statement for Astralis Pharmaceuticals Ltd. on November 16, 2001.

Previously filed with the Securities and Exchange Commission as an Exhibit to the Current Report on Form 8-K for Astralis Pharmaceuticals Ltd. on November 14, 2001.

Previously filed with the Securities and Exchange Commission as an Exhibit to the Current Report on Form 8-K for Astralis Ltd. on December 14, 2001.

Previously filed with the Securities and Exchange Commission as an Exhibit to the Preliminary Proxy Statement for Hercules Development Group Inc. on October 4, 2001.

+ Previously filed with the Securities and Exchange Commission as an Exhibit to the Registration Statement on Form SB-2 for Astralis Ltd. on March 14, 2002.

++ Previously filed with the Securities and Exchange Commission as an Exhibit to the Amendment to the Registration Statement on Form SB-2 for Astralis Ltd. on July 23, 2002.

+++ Previously filed with the Securities and Exchange Commission as an Exhibit to the Annual Report on Form 10-KSB on March 31, 2003.

(b) Reports on Form 8-K

On October 19, 2004, we filed a current report on Form 8-K reporting under Item 5.02 - Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers.

On October 29, 2004, we filed a current report on Form 8-K reporting under Item 1.01 - Entry into a Material Definitive Agreement, and Item 5.02 - Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers.

On November 3, 2004, we filed a current report on Form 8-K/A, amending our Form 8-K filed on October 29, 2004 reporting under Item 1.01 - Entry into a Material Definitive Agreement, and Item 5.02 - Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers.

On November 19, 2004, we filed a current report on Form 8-K reporting our results of operations and financial condition for the quarter ending September 30, 2004 in a press release dated November 15, 2004.

On November 24, 2004, we filed a current report on Form 8-K reporting our results of operations and financial condition for the quarter ending September 30, 2004 in a press release dated November 19, 2004.

On November 29, 2004, we filed a current report on Form 8-K reporting under Item 5.02 - Departure of Directors or Principal Officers; Election of

Directors; Appointment of Principal Officers.

On December 28, 2004, we filed a current report on Form 8-K reporting under Item 5.03 - Amendments to Articles of Incorporation or Bylaws; Changes in Fiscal Year.

Item 14. Principal Accountant Fees and Services

The information concerning our principal accounting fees required by Item 14 shall be included in the Proxy Statement to be filed relating to our 2005 Annual Meeting of Stockholders and is incorporated herein by reference, including the information set forth under the caption "Independent Auditors."

SIGNATURES

In accordance with Section 13 and 15(d) of the Securities Exchange Act of 1934, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ASTRALIS LTD.
(Registrant)

By: /s/ James Sharpe

James Sharpe
President and Chief Executive Officer

In accordance with the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jose Antonio O'Daly --- Dr. Jose Antonio O'Daly	Chairman of the Board and Chief Scientific Officer	March 30, 2005
/s/ James Sharpe --- James Sharpe	President Chief Executive Officer and Director (principal executive officer)	March 30, 2005
/s/ Michael Garone --- Michael Garone	Chief Financial Officer (principal financial and accounting officer)	March 30, 2005
/s/ Michael Ashton --- Michael Ashton	Director	March 31, 2005
/s/ Samuel Barnett	Director	March 30, 2005

Samuel Barnett		
/s/ Steven Fulda	Director	March 29, 2005
Steven Fulda		
/s/ Fabien Pictet	Director	March 31, 2005
Fabien Pictet		

ASTRALIS LTD.
(A Development Stage Entity)

INDEX TO THE FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Astralis Ltd.

We have audited the accompanying balance sheets of Astralis Ltd. (a development stage entity) as of December 31, 2004 and 2003, and the related statements of operations, stockholders' equity and cash flows for the years then ended and the period March 12, 2001 (date of inception) through December 31, 2004. These financial statements are the responsibility of the company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a

reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Astralis Ltd. as of December 31, 2004 and 2003, and the results of its operations, changes in stockholders' equity and its cash flows for the years then ended and the period March 12, 2001 (date of inception) through December 31, 2004 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has incurred net losses since inception, does not have sufficient funds to execute its business plan, estimates its current cash will last through the end of the second quarter of 2005, and reported in 2005 the results from its Phase II testing indicated no statistical difference between the Company's product and a placebo. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding those matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

L J SOLDINGER ASSOCIATES, LLC

Deer Park, Illinois
February 16, 2005

ASTRALIS LTD.
(A Development Stage Entity)
Balance Sheets

ASSETS

	December 31,	
	2004	2003
Current Assets		
Cash and cash equivalents	$ 2,312,401	$ 10
Marketable securities	--	1,374
Prepaid expense - related party	--	1,007
Prepaid expenses	70,895	84
Supplies	55,851	87
Total Current Assets	2,439,147	2,564
Intangible Assets, Net - Related Party	--	3,511
Other Intangible Assets, Net	117,923	94
Property and Equipment, Net	214,140	293
Deposits	26,763	29
	$ 2,797,973	$ 6,493

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities		
Accounts payable and accrued expenses	$ 397,762	$ 279
Total Current Liabilities	397,762	279
Commitments and Contingencies		
Stockholders' Equity		
Convertible preferred stock; Series A, $.001 par value; 3,000,000 shares authorized at 2004 and 2003; 0 and 2,000,000 issued and outstanding at 2004 and 2003, respectively (liquidation preference - $0 and $22,122,600 at 2004 and 2003, respectively)	--	2
Common stock; $.0001 par value; 150,000,000 shares authorized at 2004 and 2003; 73,173,055 and 37,538,189 issued and outstanding at 2004 and 2003, respectively	7,317	3
Additional paid-in capital	52,095,251	35,929
Deferred compensation	--	(4
Common stock subscriptions receivable	--	(24
Accumulated other comprehensive loss	--	(27
Deficit accumulated in the development stage	(49,702,357)	(29,664
Total Stockholders' Equity	2,400,211	6,214
	$ 2,797,973	$ 6,493

See the accompanying notes to financial statements.

ASTRALIS LTD.
(A Development Stage Entity)
Statements of Operations

	Year Ended December 31,		March 12, 2001 (Inception) to December 31,
	2004	2003	2004
Revenues	$ --	$ --	$ --
Operating Expenses			
Research and development - related party	4,519,400	1,721,788	16,278,822
Research and development	3,169,660	2,323,885	6,449,228
Depreciation and amortization	30,403	26,062	73,024
General and administrative	1,860,844	1,290,346	5,377,454

Total Operating Expenses	9,580,307	5,362,081	28,178,528
Loss From Operations	(9,580,307)	(5,362,081)	(28,178,528)
Investment income (loss)	(722)	60,018	179,824
Loss before income tax benefit	(9,581,029)	(5,302,063)	(27,998,704)
Income tax benefit	293,461	221,636	515,097
Net Loss	(9,287,568)	(5,080,427)	(27,483,607)
Preferred Stock Dividends	(10,750,000)	--	(22,218,750)
Net Loss to Common Stockholders	$(20,037,568)	$ (5,080,427)	$(49,702,357)
Basic and Diluted Loss per Common Share	$ (0.28)	$ (0.14)	$ (1.12)
Basic and Diluted Weighted Average Common Shares Outstanding	71,073,507	37,538,189	44,472,789

See the accompanying notes to financial statements.

ASTRALIS LTD.
(A Development Stage Entity)
Statements of Stockholders' Equity

	Preferred Stock		Common Stock	
	Shares	Amount	Shares	Amoun
Balances, March 12, 2001 (Date of Inception)	--	$ --	--	$
Members' capital contributions, 3/15/2001	--	--	25,300,000	2
Capital contributions received, 3/1 - 8/13/2001	--	--	--	
Members' contributed services, 3/15 - 6/30/2001	--	--	--	
Members' capital contributions,				

9/1/2001	--	--	2,700,000	
Warrants to purchase 6,300,000 shares of common stock at $1.60 per share issued in private placement	--	--	--	
Common stock issuable for consulting services, 9/1/2001; 500,000 shares	--	--	--	
Common stock issued in private placement net of issuance costs, 11/13/2001; 2,076,179 shares at $1.60 per share	--	--	2,076,179	
Warrants to purchase 415,237 shares of common stock at $4.00 per share issued in private placement, 11/13/2001	--	--	--	
Net assets and liabilities acquired in merger with Hercules	--	--	7,512,000	
Preferred stock issued, net of issuance costs, 12/10/2001; 1,000,000 shares at $10.00 per share	1,000,000	1,000	--	
Preferred stock dividend, 12/10/2001	--	--	--	
Options to purchase 200,000 shares of common stock at $1.77 (based on valuation) issued for legal services, 12/31/2001	--	--	--	
Options to purchase 100,000 shares of common stock at $1.77 (based on valuation) issued for consulting services, 12/31/2001	--	--	--	
Amortization of deferred compensation	--	--	--	
Net loss	--	--	--	
Total Comprehensive Loss				
Balance, December 31, 2001	1,000,000	$ 1,000	37,588,179	$ 3

See the accompanying notes to financial statements.

ASTRALIS LTD.
(A Development Stage Entity)
Statements of Stockholders' Equity

	Subscription Receivable	Deferred Compensation	Accumulated Other Comprehensive Loss	Defici Accumula During Developm Stage
Balances, March 12, 2001 (Date of Inception)	$ --	$ --	$ --	$
Members' capital contributions, 3/15/2001	(33,183)	--	--	
Capital contributions received, 3/1 - 8/13/2001	33,183	--	--	
Members' contributed services, 3/15 - 6/30/2001	--	--	--	
Members' capital contributions, 9 /1/2001	(1,350,000)	--	--	
Warrants to purchase 6,300,000 shares of common stock at $1.60 per share issued in private placement	--	--	--	
Common stock issuable for consulting services, 9/1/2001; 500,000 shares	--	--	--	
Common stock issued in private placement net of issuance costs, 11/13/2001; 2,076,179 shares at $1.60 per share	--	--	--	
Warrants to purchase 415,237 shares of common stock at $4.00 per share issued in private placement, 11/13/2001	--	--	--	
Net assets and liabilities acquired in merger with Hercules	--	--	--	
Preferred stock issued, net of issuance costs, 12/10/2001; 1,000,000 shares at $10.00 per share	--	--	--	
Preferred stock dividend, 12/10/2001	--	--	--	(2,120,
Options to purchase 200,000 shares of common stock at $1.77 (based on valuation) issued for legal services, 12/31/2001	--	(354,000)	--	
Options to purchase 100,000 shares of common stock at $1.77 (based on valuation) issued for consulting services, 12/31/2001	--	(177,000)	--	
Amortization of deferred compensation	--	132,750	--	
Net loss	--	--	--	(4,075,

Total Comprehensive loss				
Balance, December 31, 2001	$(1,350,000)	$ (398,250)	$ --	$(6,195,

See the accompanying notes to financial statements.

ASTRALIS LTD.
(A Development Stage Entity)
Statements of Stockholders' Equity

	Preferred Stock		Common Stock	
	Shares	Amount	Shares	Amou
Balances Brought Forward	1,000,000	$ 1,000	37,588,179	$
Oversubscription of common stock issued in private placement, 11/13/2001; 49,990 shares cancelled at $1.60 per share, 1/24/2002	--	--	(49,990)	
Preferred stock issue, net of issuance costs, 1/31/2002; 250,000 shares at $10.00 per share	250,000	250	--	
Preferred stock issue, net of issuance costs, 4/30/2002; 250,000 shares at $10.00 per share	250,000	250	--	
Preferred stock dividend, April 30, 2002	--	--	--	
Preferred stock issue, net of issuance costs, 7/31/2002; 250,000 shares at $10.00 per share	250,000	250	--	
Collection of subscription receivable	--	--	--	
Options issued for consulting services, 9/10/2002; 15,000 options at $0.38 per option, based on valuation	--	--	--	
Preferred stock dividend, 12/10/2002	--	--	--	
Amortization of deferred compensation	--	--	--	

Fair value adjustment on deferred compensation	--	--	--	
COMPREHENSIVE LOSS				
Net loss	--	--	--	
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	--	--	--	
Total Comprehensive Loss				
Balance, December 31, 2002	1,750,000	$ 1,750	37,538,189	$

See the accompanying notes to financial statements.

ASTRALIS LTD.
(A Development Stage Entity)
Statements of Stockholders' Equity

	Subscription Receivable	Deferred Compensation	Accumulated Other Comprehensive Loss	Deficit Accumulate During th Developme Stage
Balances Brought Forward	$ (1,350,000)	$ (398,250)	$ --	$ (6,195,3
Oversubscription of common stock issued in private placement, 11/13/2001; 49,990 shares cancelled at $1.60 per share, 1/24/2002	--	--	--	
Preferred stock issue, net of issuance costs, 1/31/2002; 250,000 shares at $10.00 per share	--	--	--	
Preferred stock issue, net of issuance costs, 4/30/2002; 250,000 shares at $10.00 per share	--	--	--	
Preferred stock dividend, April 30, 2002	--	--	--	(270,0
Preferred stock issue, net of issuance costs, 7/31/2002; 250,000 shares at $10.00 per share	--	--	--	

Collection of subscription receivable	465,000	--	--	
Options issued for consulting services, 9/10/2002; 15,000 options at $0.38 per option, based on valuation	--	(5,700)	--	
Preferred stock dividend, 12/10/2002	--	--	--	(9,078,7
Amortization of deferred compensation	--	34,254	--	
Fair value adjustment on deferred compensation	--	357,532	--	
COMPREHENSIVE LOSS				
Net loss	--	--	--	(9,040,2
Other comprehensive loss:				
Unrealized loss on available-for-sale securities	--	--	(15,181)	
Total Comprehensive Loss				
Balance, December 31, 2002	$ (885,000)	$ (12,164)	$ (15,181)	$(24,584,3

See the accompanying notes to financial statements.

ASTRALIS LTD.
(A Development Stage Entity)
Statements of Stockholders' Equity

	Preferred Stock		Common Stock	
	Shares	Amount	Shares	Amoun
Balances Brought Forward	1,750,000	$ 1,750	37,538,189	$ 3
Preferred stock issue, net of issuance costs, 1/31/2003; 250,000 shares at $10.00 per share	250,000	250	--	
Collection of subscription receivable	--	--	--	
Reduction of subscription receivable, in lieu of payment for services	--	--	--	

Amortization of deferred compensation	--	--	--	
Fair value adjustment on deferred compensation	--	--	--	
Offering cost for January 2004 private placement	--	--	--	
COMPREHENSIVE LOSS				
Net loss	--	--	--	
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	--	--	--	
Total Comprehensive Loss				
Balance, December 31, 2003	2,000,000	$ 2,000	37,538,189	$ 3

See the accompanying notes to financial statements.

ASTRALIS LTD.
(A Development Stage Entity)
Statements of Stockholders' Equity

	Subscription Receivable	Deferred Compensation	Accumulated Other Comprehensive Loss	Deficit Accumulat During th Developme Stage
Balances Brought Forward	$ (885,000)	$ (12,164)	$ (15,181)	$(24,584,3
Preferred stock issue, net of issuance costs, 1/31/2003; 250,000 shares at $10.00 per share	--	--	--	
Collection of subscription receivable,	825,000	--	--	
Reduction of subscription receivable, in lieu of payment for services	36,000	--	--	
Amortization of deferred compensation	--	25,663	--	

Fair value adjustment on deferred compensation	--	(18,321)	--	
Offering cost for January 2004, private placement	--	--	--	
COMPREHENSIVE LOSS				
Net loss	--	--	--	(5,080,4
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale Securities, net	--	--	(12,517)	
Total Comprehensive Loss				
Balance, December 31, 2003	$ (24,000)	$ (4,822)	$ (27,698)	$(29,664,7

See the accompanying notes to financial statements.

ASTRALIS LTD.
(A Development Stage Entity)
Statements of Stockholders' Equity

	Preferred Stock		Common Stock	
	Shares	Amount	Shares	A
Balances Brought Forward	2,000,000	$ 2,000	37,538,189	$
Common stock issue, net of issuance costs, Jan -Feb 2004 at $0.50 per unit	--	--	10,459,866	
Collection of subscription receivable	--	--	--	
Conversion of Preferred Stock, Series A	(2,000,000)	(2,000)	25,000,000	
Preferred stock dividend	--	--	--	
Common stock issued, in lieu of payment for services	--	--	150,000	
Call option assigned, in lieu of payment for services	--	--	--	

Amortization of deferred compensation	--	--	--	
Stock options exercised	--	--	25,000	
COMPREHENSIVE LOSS				
Net loss	--	--	--	
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	--	--	--	
Total Comprehensive Loss				
Balance, December 31, 2004	--	$ --	73,173,055	$

See the accompanying notes to financial statements.

ASTRALIS LTD.
(A Development Stage Entity)
Statements of Stockholders' Equity

	Subscription Receivable	Deferred Compensation	Accumulated Other Comprehensive Loss	Deficit Accumulated During the Development Stage
Balances Brought Forward	$ (24,000)	$ (4,822)	$ (27,698)	$(29,664,789
Common stock issue, net of issuance costs, Jan -Feb 2004 at $2.00 per share	--	--	--	--
Collection of subscription receivable,	24,000	--	--	--
Conversion of Preferred Stock, Series A	--	--	--	--
Preferred stock dividend	--	--	--	(10,750,000
Common stock issued, in lieu of payment for services	--	--	--	--
Call option assigned, in lieu of payment for services	--	--	--	--

Amortization of deferred compensation	--	4,822	--	--
Stock options exercised	--	--	--	--
COMPREHENSIVE LOSS				
Net loss	--	--	--	(9,287,568
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities, net	--	--	27,698	--
Total Comprehensive Loss				
Balance, December 31, 2004	$ --	$ --	$ --	$(49,702,357

See the accompanying notes to financial statements.

ASTRALIS LTD.
(A Development Stage Entity)
Statements of Cash Flows

	Year Ended December	
	2004	200
Cash Flows from Operating Activities		
Net loss	$ (9,287,568)	$ (5,08
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	867,902	84
Impairment of intangible asset	2,797,612	
Amortization of net premium paid on investments	--	
Dividend income reinvested	(117,219)	(7
Members' contributed salaries	--	
Research and development service fee netted against proceeds received from preferred stock issuance	--	2
Operating expenses paid by related parties on behalf of company	--	
Amortization of deferred compensation	4,822	2
Investor relation fees netted against subscription receivable	24,000	3
Compensatory common stock	75,000	
Assignment of call option	376,508	
Loss on sale of available-for-sale securities and fixed asset retirement	129,832	2
Changes in assets and liabilities		
Prepaid expenses	1,059,838	97
Interest receivable	--	
Supplies	31,186	(5

Deposits	3,190	
Accounts payable and accrued expenses	77,228	(
Net Cash Used in Operating Activities	(3,957,669)	(3,27
Cash Flows from Investing Activities		
Purchases of available-for-sale securities	(4,300,010)	(1,91
Proceeds from sale of available-for-sale securities	5,690,970	1,78
Expenditures related to patent	(26,947)	(3
Insurance proceeds from claim	4,113	
Purchases of property and equipment	(74,157)	(6
Net Cash Used in Investing Activities	1,293,969	(23
Cash Flows from Financing Activities		
Repurchase of common stock	--	
Collection of subscription receivable	--	82
Proceeds from exercise of stock options	11,250	
Issuance of common stock, net of offering and transaction costs	4,954,191	
Issuance of preferred stock	--	2,48
Private placement offering costs	--	(1
Net Cash Provided by Financing Activities	4,965,441	3,28
Net Increase (Decrease) in Cash and Cash Equivalents	2,301,741	(21
Cash and Cash Equivalents, Beginning of Period	10,660	22
Cash and Cash Equivalents, End of Period	$ 2,312,401	$ 1

See the accompanying notes to financial statements.

ASTRALIS LTD.
(A Development Stage Entity)
Notes to Financial Statements

NOTE 1 - DESCRIPTION OF BUSINESS

Nature of Operations

Astralis, Ltd. (the "Company") is an emerging stage biotechnology company, based in New Jersey and incorporated under the laws of the State of Delaware, which primarily engages in research and development of treatments for immune system disorders and skin diseases. The Company is currently developing two products. Its primary product, Psoraxine(R), administered by intramuscular injection, is an innovative immunotherapeutic product under development for the treatment of psoriasis. The Company's second product is for the treatment of arthritis. The Company is also engaged in research on the possible development of the technology underlying Psoraxine(R) for the treatment of other indications, such

as eczema and leishmaniasis.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The Company's financial statements are prepared on the accrual basis of accounting in accordance with United States generally accepted accounting principles ("US GAAP").

Development Stage Enterprise

The Company is a Development Stage Enterprise, as defined in Statement of Financial Accounting Standards ("SFAS") No. 7 "Accounting and Reporting for Development Stage Enterprises." Under SFAS No. 7, certain additional financial information is required to be included in the financial statements for the period from inception of the Company to the current balance sheet date.

Since the inception of the Company, management has been in the process of performing research and development activities, fulfilling FDA requirements in order to get approval on Psoraxine(R), and the raising of capital through private placement stock offerings.

Use of Estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents include cash on hand and investments in money market funds. The Company considers all highly-liquid instruments with an original maturity of 90 days or less at the time of purchase to be cash equivalents.

Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash deposits at financial institutions. To mitigate this risk, the Company places its cash deposits only with high credit quality institutions.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Property and Equipment

Furniture and equipment are recorded at cost, less accumulated depreciation computed on a straight-line basis over the estimated useful lives of the respective assets. Depreciation is computed using a four-year life for computer and office equipment, three to four years for lab equipment, five-year for automobile, seven-year for furniture and fixtures and three-year for leasehold

improvements.

Income Taxes

Income taxes are recorded in the period in which the related transactions are recognized in the financial statements, net of the valuation allowances, which have been recorded against deferred tax assets. Deferred tax assets and liabilities are recorded for the expected future tax consequences of temporary differences between the tax basis and the financial reporting of assets and liabilities. Net deferred tax assets and liabilities, relating primarily to federal and state net operating loss carryforwards and research and development credits that have been deferred for tax purposes have also been recorded. A valuation reserve has been recorded to offset a portion of the deferred tax benefit (except for amount realized through the sale of a portion of the Company's New Jersey net operating loss) because management has determined it is more likely than not that the deferred tax assets will not be realized. (See Note 7.)

Fair Value of Financial Instruments

The Company's financial instruments, including cash and cash equivalents, accounts payable and accrued expenses, are carried at cost, which approximates fair value.

Stock-Based Compensation Arrangements

The Company applies the intrinsic value method of accounting prescribed by Accounting Principles Board Opinion No. 25, "Accounting For Stock Issued To Employees," and related interpretations, in accounting for its stock-based grants to employees and directors. Under the intrinsic value method of accounting, compensation expense is recorded on the date of grant only if the current market price of the underlying stock exceeds the exercise price. The Company applies the disclosure provisions specified in SFAS No. 148, "Accounting For Stock-Based Compensation - Transition and Disclosure - an Amendment of SFAS 123." The Company applies SFAS No. 123, "Accounting for Stock-Based Compensation," in accounting for stock-based grants to non-employees.

The following table illustrates the effect on net loss and earnings per share if the Company had applied the fair value recognition provisions of SFAS 123, "Accounting for Stock-Based Compensation," to stock-based compensation.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

	Year Ended December 31, Year Ended	
	2004	2003
Net loss, as reported	$(20,037,568)	$ (5,080,4
Add:		
Stock-based compensation expense included in reported net		

loss determined under APB No. 25, net of related tax effects	--	
Deduct:		
Total stock-based director compensation expense determined under fair-value-based method for all awards, net of related tax effects	29,495	11,5
Pro forma net loss	$(20,067,063)	$ (5,092,0
Loss per share:		
Basic - as reported	$ (0.28)	$ (0.
Basic - pro forma	$ (0.28)	$ (0.

These pro forma amounts may not be representative of future disclosures since the estimated fair value of stock options is amortized to expense over the vesting period and additional options may be issued in future years. The estimated fair value of each option granted was calculated using the Black-Scholes option-pricing model. The following summarizes the weighted average of the assumptions used in the model.

	2004	2003
Risk free rate	4.13%	2.1%
Expected years until exercise	9.614	3.0
Expected stock volatility	100.0%	100.0%
Dividend yield	--	--

Loss Per Share

Loss per common share is calculated in accordance with SFAS No. 128, Earnings Per Share. Basic loss per common share is computed based upon the weighted average number of shares of common stock outstanding for the period and excludes any potential dilution. Shares associated with stock options, warrants and convertible preferred stock are not included because their inclusion would be antidilutive (i.e., reduce the net loss per share).

The common shares potentially issuable arising from these instruments, which were outstanding during the periods presented in the financial statements, consisted of:

	2004	2003
Options	1,118,000	365,000
Warrants	18,151,891	6,780,237
Convertible preferred stock	--	12,500,000
	19,269,891	19,645,237

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Segment Information

The Company has determined it has one reportable operating segment as defined by SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information."

Research and Development Costs

The cost of research, development and product improvement expenditures, which includes depreciation of the Company's laboratory, amortization and impairment of the technology access option, are charged to expense as they are incurred. Research, development and product improvement costs included in operating expenses amounted to $7,689,060 and $4,045,673 for the years ending December 31, 2004 and 2003, respectively; and $22,728,050 for the period from March 12, 2001 (date of inception) to December 31, 2004.

Included in this amount were payments to related parties (see Note 11). Also included in the December 31, 2004 and for the period from March 12, 2001 (date of inception) to December 31, 2004 amount is an impairment of intangible assets of $2,797,612. (see Note 5).

Recently Issued Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board issued SFAS No. 123 (revised 2004), Share-Based Payment, which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation. SFAS 123(R) supersedes Accounting Principles Board ("APB") Opinion No. 25, Accounting for Stock Issued to Employees. Generally, the approach in SFAS 123(R) is similar to the approach described in Statement 123. However, Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. Statement 123(R) must be adopted no later than January 1, 2006 and early adoption is permitted in periods in which financial statements have not yet been issued.

As required, the Company will adopt SFAS No. 123(R) no later than January 1, 2006. Under SFAS No. 123(R), the Company may either recognize compensation cost for share-based payments to employees based on the grant-date fair value from the beginning of the period in which the provisions are first applied, without restating periods prior to adoption, or may elect to restate prior periods by recognizing compensation costs in the amounts previously reported in the pro-forma footnote disclosures under the provisions of SFAS 123. The Company is evaluating the impact of the two adoption methods and as yet has not determined which method we will utilize.

The Company cannot estimate the impact of adopting Statement No. 123(R) because it will depend on levels of share-based payments granted in the future but, based solely upon the pro-forma disclosures for prior periods, we believe that the impact will not be material to our results of operations.

NOTE 3 - GOING CONCERN

The Company incurred net losses to common stockholders of $20,037,568 and $49,702,357 for the year ended December 31, 2004 and for the period March 12, 2001 (date of inception) to December 31, 2004, respectively. Included in these net losses were non-cash preferred stock dividends generated from beneficial conversion features of preferred stock in the amounts of $10,750,000 for the year ended December 31, 2004 and $22,218,750 in the cumulative net loss (see Note 8).

The Company estimates it has sufficient funds to meet operating expenses and

capital requirements through the end of the second quarter of 2005.

NOTE 3 - GOING CONCERN (Continued)

Pharmaceutical products must undergo an extensive process, including testing in compliance with U.S. Food and Drug Administration ("FDA") regulations, before they can be commercially sold and distributed in the United States. FDA testing occurs in various phases over a multiple number of years. The Company expects to continue clinical testing of Psoraxine in 2005 and beyond. The Company will need significant additional funds to complete all of the testing required by the FDA. Currently, the Company has no products approved for commercial sale and therefore no means to generate revenue.

On March 14, 2005, the Company issued a press release to disclose the results of its Phase II study for Psoraxine. The Phase II study of its novel immuno-stimulatory product for the treatment of Psoriasis indicated no statistical difference between the Company's product and a placebo. In the study, Psoraxine was found to be safe and well tolerated.

The Company is currently analyzing the data from its Phase II study to understand why the results differ from the long-term improvement of the more than 2,700 patients who were treated with Psoraxine in pre-clinical studies and whether a different approach, including evaluating a longer course of therapy and/or modifications to the formulation, may yield an outcome that is more consistent with results from pre-clinical studies.

Consequently, the aforementioned items raise substantial doubt about the Company's ability to continue as a going concern.

Management plans to raise additional capital through private placement equity offerings in 2005. These funds, in addition to its cash held at December 31, 2004, will be needed in order to finance the Company's currently anticipated needs for operating and capital expenditures for 2005, including the cost to evaluate the results of the Phase II study, continue clinical trials of Psoraxine(R) and initiate development of pipeline products to treat arthritis and leishmaniasis. The Company will also need to raise significant additional funds from outside sources in future years in order to complete existing and future phases of FDA required testing.

The Company's ability to continue as a going concern is dependent upon raising capital through debt and equity financing. There can be no assurance that the Company will successfully raise the required future financing on terms desirable to the Company or that the FDA will approve Psoraxine for use in the United States. If the Company does not obtain the needed funds, it will likely be required to delay development of its products, alter its business plan, or in the extreme situation, cease operations. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

NOTE 4 - MARKETABLE SECURITIES

The Company's marketable equity securities consisted of certificates of deposit, fixed income funds that have a readily determinable fair market value. Management determines the appropriate classifications of its investments using SFAS No. 115 "Accounting for Certain Investments in Debt and Equity Securities"

at the time of purchase, and re-evaluates such determinations at each balance sheet date.

The securities reflected in these financial statements are deemed by management to be "available-for-sale" and, accordingly, are reported at fair value, with unrealized gains and losses reported in other comprehensive income and reflected as a separate component within the Stockholder's Equity section of the balance sheets. Realized gains and losses on securities available-for-sale are included in other income/expense and, when applicable, are reported as a reclassification adjustment, net of tax, in other comprehensive income. Gains and losses on the sale of available-for-sale securities are determined using the specification method.

The Company had no available for sale securities as of December 31, 2004.

NOTE 4 - MARKETABLE SECURITIES (Continued)

As of December 31, 2003, available-for-sale securities consist of the following:

	Due	Amortized Cost	Gross Unrealized Loss	Gross Unrealized Gains	Fair
Fixed Income Fund	Current	$ 1,401,872	$ (27,740)	$ 42	$ 1,3
		$ 1,401,872	$ (27,740)	$ 42	$ 1,3

The Company's investment income (loss) consists of:

	Years Ended December 31,	
	2004	2003
Interest income	$ 127,409	$ 120,668
Realized loss from disposal of securities	(128,131)	(23,760)
Bad debt expense	--	(36,890)
	$ (722)	$ 60,018

NOTE 5 - INTANGIBLE ASSETS

The Company's policy is to capitalize the costs of purchased and internally developed patents and those expenses in connection with patent rights licensed to the Company. The life of the patent is 20 years from the date the patent is

applied for or 17 years from when it is granted, whichever is longer. The Company's policy is to capitalize direct costs related to the rights it has licensed, and amortize them on a straight-line basis over the remaining portion of the 20-year period, which commenced on March 16, 2001, the date the application was filed for the patent the Company has licensed

The Company paid $5,000,000 for a technology access option from SkyePharma PLC ("SkyePharma"). This option gives the Company the right, until December 10, 2008, to enter into a non-exclusive license agreement to utilize any of three drug delivery systems of SkyePharma in connection with any drugs it develops to treat two specific immunotherapies. Upon exercise of the option, the Company will be required to pay a license fee of 5% of net sales of any product utilizing the drug delivery systems. All other terms of the license agreement will be determined upon exercise of the option. In addition, any use of the delivery systems after December 10, 2008 will need to be negotiated under a new licensing agreement at that time.

Management has taken the position that the technology access option fee is a license fee which allows the Company, prior to commercialization of its drugs, to utilize the established delivery system technologies of SkyePharma to test for viability and enhancement of the Company's Psoraxine vaccine. In accordance with Financial Accounting Standard No. 2 - Research and Development Costs ("SFAS No. 2"), the Company has capitalized the technology access option as a research and development intangible asset and is amortizing it over its seven-year life. The Company evaluates this intangible annually for impairment under SFAS 144 "Accounting for the Impairment or Disposal of Long-Lived Assets." The Company has determined that as of December 31, 2004, the technology access option fee exceeded its fair market value and consequently the Company recorded impairment charges in the amount of $2,797,612 in 2004.

NOTE 5 - INTANGIBLE ASSETS - (Continued)

The Company has amortized $6,362 and $2,892 of patent costs and $714,288 and $714,288 of the cost of the technology option license in 2004 and 2003, respectively. The amortization and impairment related to the technology option license is recorded as research and development cost as required by SFAS No. 2.

Intangible assets consisted of the following at December 31,

	2004	2003
Patent	$ 130,109	$ 100,464
Technology access fee	5,000,000	5,000,000
Less impairment	(2,797,612)	--
Less accumulated amortization	(2,214,574)	(1,493,924)
	$ 117,923	$ 3,606,540

Amortization expense related to the patents is expected to be approximately $6,400 per year for each of the succeeding five years.

NOTE 6 - PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31,

	2004	2003
Furniture and Fixtures	$ 28,281	$ 28,281
Computer Equipment	30,477	21,803
Leasehold Improvements	199,741	196,544
Lab Equipment	299,066	236,781
Automobiles	--	8,945
	$ 557,565	$ 492,354
Accumulated depreciation and amortization	(343,425)	(199,305)
	$ 214,140	$ 293,049

Depreciation expense amounted to $147,252 and $130,574 for the years ended December 31, 2004 and 2003, respectively. The depreciation related to the Company's laboratory and related equipment is recorded as research and development as required by SFAS No. 2.

NOTE 7 - INCOME TAXES

Deferred income taxes reflect the net tax effects of temporary timing differences between the carrying amounts of assets and liabilities reflected on the financial statements and the amounts used for income tax purposes. The tax effects of temporary differences and net operating loss carryforwards and tax credits that give rise to significant portions of the deferred tax assets recognized are presented below:

	December 31, 2004	2003
Deferred tax assets :		
Prepaid research and development	$ --	$ 798,800
Deferred compensation	76,500	77,000
Accumulated depreciation and amortization	1,613,200	332,000
Research and development credits carryforward	1,974,300	1,125,400
Federal and state deferred tax benefit arising from net operating loss carryforwards	8,370,600	5,612,500
	12,034,600	7,945,700

Less valuation allowance	(12,034,600)	(7,945,700)
Total deferred tax assets	$ --	$ --

As of December 31, 2004, the Company had losses, which resulted in net operating loss carryforwards for tax purposes amounting to approximately $22,000,000 that may be offset against future taxable income. These carryforwards start to expire in 2021. The Company generated federal research and development credits of $1,350,300 that will start to expire in 2021 and state credits of $624,000 that will start to expire in 2008. However, these carryforwards and credits may be significantly limited due to changes in the ownership of the Company as a result of future equity offerings.

Recognition of the benefits of the deferred tax assets and liabilities will require that the Company generate future taxable income. There can be no assurance that the Company generates any earnings or any specific level of earnings in future years. Therefore, the Company has established a valuation allowance for deferred tax assets (net of liabilities) of approximately $12,034,600 and $7,945,700 as of December 31, 2004 and 2003.

In 2004 and 2003, the Company sold $3,791,489 and $2,863,511, respectively, of its gross New Jersey net operating loss carryforwards under the State of New Jersey's Technology Business Tax Certificate Transfer Program (the "Program"). The Program allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of net operating loss carryforwards and defined research and development tax credits for cash. The proceeds from the sale of the Company's carryforwards were $293,461 and $221,600, respectively (net of fees) and the amount was recorded as a tax benefit in the statements of operations. The State of New Jersey renews the Program annually and limits the aggregate proceeds of the program to $10,000,000. Due to the uncertainty at any time as to the Company's ability to effectuate the sale of available New Jersey net operating losses, and since the Company has no control or influence over the Program, the benefits are recorded once the agreement with the counterpart is signed and the sale is approved by the State.

In accordance with federal income tax regulations, the net loss incurred by Astralis, LLC from inception to the date of its merger with the Company has been excluded from the benefits of the net operating loss carryforwards reflected in this footnote.

NOTE 7 - INCOME TAXES (Continued)

The following table presents the principal reasons for the difference between the Company's effective tax rates and the United States federal statutory income tax rate of 34%.

	December 31, 2004	2003

Federal income tax benefit at statutory rate	$ 3,257,550	$ 1,802,700
State income tax benefit (net of effect of federal benefit)	446,600	296,300
Non-deductible expenses	(170,650)	(130,300)
Research and development credit	848,900	688,200
Valuation allowance before realization of state benefit	(4,382,400)	(2,656,900)
Benefit from sale of state net operating loss	293,500	221,600
Income Tax Benefit	$ 293,500	$ 221,600
Effective Income Tax Rate	(9%)	(13%)

NOTE 8 - CAPITAL STOCK ACTIVITY

Common Stock

In 2001 Astralis LLC and the Company merged and this transaction was treated as a recapitalization of the Company, whereby the Company issued to the members of Astralis, LLC, 28,000,000 shares of common stock and warrants to purchase 6,300,000 shares of Company common stock for $1.60 per share in a one-for-one exchange for all of the outstanding 28,000,000 Astralis, LLC member units of ownership and 6,300,000 options to purchase member units.

Prior to the Merger

Astralis LLC issued 25,300,000 units on April 25, 2001 to various members for an aggregate subscription receivable amount of $33,183. During the year, the members paid $33,183 on behalf of the Company to satisfy their subscription receivable.

In April 2001, the Company issued warrants to purchase 75,000 shares of common stock at an exercise price of $1.75 per share. These warrants expired in April 2004.

On September 1, 2001, five new members were admitted as members of the LLC through the execution of a subscription agreement. These new members subscribed to units ("Units") from Astralis LLC consisting of an aggregate of 2,700,000 membership interests (the "Membership Interests") in Astralis LLC and 6,300,000 options to purchase additional Membership Interests in Astralis LLC for an exercise price of $1.60 per Membership Interest.

On November 13, 2001, the aforementioned Units were exchanged for an aggregate of 2,700,000 shares of our common stock and warrants to purchase 6,300,000 shares of common stock at an exercise price of $1.60 per share. The aggregate purchase price for such Units was $1,350,000 and was paid with subscription notes. Warrants to purchase 3,150,000 shares of common stock, as amended, were to expire on December 13, 2004 and 3,150,000 expire November 13, 2006. The 3,150,000 warrants that were set to expire on December 13, 2004 were extended to February 18, 2005 and subsequently extended to March 11, 2005 when they expired.

NOTE 8 - CAPITAL STOCK ACTIVITY (Continued)

In September 2001, Astralis, LLC granted 500,000 membership units to a consultant in return for services rendered. The membership units were subsequently exchanged for shares of common stock of the Company. The cost of the services, based on an independent valuation of the units granted, which amounted to $135,000, were recorded at the time the services were rendered in 2001.

Subsequent to Merger

In November 2001, the Company completed a $3,321,887 private placement offering pursuant to which it sold 103.81 units at $32,000 per unit for an aggregate amount of $3,321,887. Each unit consisted of 20,000 shares of common stock and warrants to purchase 4,000 shares of the Company's common stock at $4.00 per share. The warrants expire on November 13, 2006. The holders of these shares of common stock and warrants received registration rights. The Company was required to file a registration statement by March 13, 2002 to register the sale of these shares and the shares underlying the warrants. Upon consummation of the private placement, the Company paid a $100,000 investment banking fee and entered into an agreement for future investment banking services amounting to $144,000, payable in 24 equal monthly installments of $6,000.

In January 2002, the Company agreed to amend a subscription agreement with one of the investors who participated in the November 2001 private placement offering. The Company consented to reduce the number of shares in the subscription agreement by 49,990 shares of common stock. The Company cancelled the respective shares and returned the corresponding amount of funds to the investor amounting to $80,000.

In 2002 and 2003, the Company collected $465,000 and $825,000 in cash of the subscription receivables, respectively. In April 2003, the Company entered into the Amended Investor Relation Agreement with one of the stockholders who has outstanding subscription receivable with the Company. The Company agreed to receive services in lieu of payment of the outstanding subscription receivable in the amount of $60,000. In 2004 and 2003, the Company received services valued at $24,000 and $36,000, respectively.

On December 15, 2003, the Company amended its Articles of Incorporation to authorize the issuance of 150,000,000 shares of common stock, $0.0001 par value per share, and 3,000,000 shares of Series A preferred stock, $0.001 par value of which 73,173,055 shares of common and 0 share of Series A preferred were outstanding as of December 31, 2004.

On January 20, 2004, the Company closed a private placement from which it received gross proceeds of approximately $4,080,000. The transaction consisted of the sale to accredited investors of units consisting of 8,159,964 shares of common stock and warrants to purchase 8,159,964 shares of common stock. The warrants have an exercise price of $0.73 and expire in four years.

On February 19, 2004, the Company closed the second round of its private placement from which it received $1,150,000. The transaction consisted of sales to accredited investors of units consisting of 2,299,902 shares of common stock and warrants to purchase 2,299,902 shares of common stock. The warrants have an exercise price of $0.73 and expire in four years.

FPP Capital Advisors whose sole shareholder is a director of the Company was paid a consulting fee in the amount of $261,496 in February 2004 for the consulting services related to the private placement completed in 2004. In addition, the related party and his assignees received warrants to purchase an aggregate of 418,394 shares of the Company's common stock at $0.50 per share and warrants to purchase an aggregate of 418,394 shares of the Company's common

stock at $0.73 per share. An additional consulting fee equal to 5% of proceeds received will be paid upon exercise of the warrants issued in the private placements. The warrants expire in four years.

NOTE 8 - CAPITAL STOCK ACTIVITY (Continued)

The Company issued to FPP Capital Advisors (a related party) 150,000 shares of common stock and warrants to purchase 150,000 shares of common stock for consulting services valued at $75,000. The warrants have an exercise price of $0.73 and expire in five years. In addition, in connection with the conversion by SkyePharma of its shares of the Company's Series A Preferred Stock, the Company assigned to FPP Capital Advisors, as compensation, 10% of the call option provided to the Company under the call option agreement dated January 20, 2004 between the Company and SkyePharma. Accordingly, the Company recorded a non-cash charge of $376,508 in June 2004.

On July 9, 2004 a director of the Company exercised options to purchase 25,000 shares of common stock at $0.45 a share. The shares issued remain restricted.

Preferred Stock

On December 13, 2001, the Company authorized 2,000,000 shares of preferred stock to be designated as "Series A Convertible Preferred Stock" ("Series A Preferred") with a $0.001 par value per share. If the Company declares a dividend, holders of each share of Series A Preferred are entitled to non-cumulative cash dividends which will be the greater of i) 6% of the preferred share purchase price; or ii) the amount such holders would have received had the holders converted to common stock immediately prior to record date for payment of a dividend to holders of common stock. No dividend can be declared or paid on common stock without an equal or greater dividend being paid or declared on the Series A Preferred. Holders of each share of Series A Preferred were entitled to vote on all matters at stockholder meetings. Holders of each share of the Series A Preferred could convert their shares to common stock at an initial conversion price of $2.50. The conversion price could be adjusted and reset as set forth in the purchase agreement for the Series A Preferred.

On December 10, 2001, the Company and SkyePharma entered into a purchase agreement whereby SkyePharma agreed to purchase 2,000,000 shares of Series A Preferred at a price of $10 per share over a 13-month period with five separate closings. On December 10, 2002, the one-year anniversary of the agreement, SkyePharma received registration rights on the common stock underlying its Series A Preferred shares. The first closing occurred in December 2001 and the Company sold 1,000,000 shares of Series A Preferred for a purchase price of $10,000,000.

The second, third and fourth closing occurred in January 2002, April 2002, and July 2002. On each closing, the Company sold 250,000 shares of Series A Preferred for a purchase price of $2,500,000. The final 250,000 shares of Series A Preferred totaling $2,500,000 closed on January 31, 2003.

The Company's stock price on December 10, 2001 was $3.03; consequently, pursuant to the requirements of the Emerging Issues Task Force ("EITF") 98-5 "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently

Adjustable Conversion Ratios," as amended by EITF 00-27, the issuance of the Series A Preferred, which was convertible initially at $2.50 per share at any time, resulted in a beneficial conversion feature recorded as a preferred stock dividend in the amount of $2,120,000.

The Company's stock price on April 30, 2002 was $2.77; consequently, the issuance of the Series A Preferred, which was convertible initially at $2.50 per share at any time, resulted in a beneficial conversion feature recorded as a preferred stock dividend in the amount of $270,000.

Since the conversion price of the Series A Preferred was subject to reset provisions as described above, there was a beneficial conversion feature applicable to the Series A Preferred. Using the potential conversion price of $1.60 for the first anniversary date as specified in the purchase agreement, the beneficial conversion feature resulted in an additional preferred stock dividend of $9,078,750 in December 2002.

NOTE 8 - CAPITAL STOCK ACTIVITY (Continued)

On January 20, 2004, Skyepharma converted all of its outstanding shares of Series A Preferred Stock of the Company into 25,000,000 shares of common stock at a reduced conversion price of $0.80 per share. Skyepharma agreed that up to 12,500,000 shares of its common stock issued upon conversion of the Series A Preferred Stock will be subject to a call option at the discretion of the Company upon completion of an agreed upon milestone at a premium in excess of the conversion price. The call option can be exercised on or after July 21, 2004. In connection with this transaction and in accordance with SFAS 84, "Induced Conversions of Convertible Debt, an Amendment of APB Opinion No. 26" the Company recorded a non-cash preferred stock dividend in January 2004 amounting to $10,750,000.

On the closing date of conversion, January 20, 2004, the Company and other original stockholders amended the stockholders agreement dated as of December 10, 2001. After the date of that Amendment, the Board of Directors is required to be comprised of at least seven directors and include at least two independent directors. Per the Amendment, SkyePharma shall have the right to nominate one director, who shall initially be Michael Ashton. From the date of the Amendment until the third anniversary, Jose Antonio O'Daly, Mike Ajnsztajn and Gaston Liebhaber (the "Founders"), each has the right to nominate one director. The Founders will initially be directors. The Agreement will terminate upon the later of (i) the SkyePharma Termination Date or (ii) the third anniversary of this Amendment, which is January 20, 2007. Further, this agreement may be terminated by the mutual written consent. "The SkyePharma Termination Date" is the date on which SkyePharma no longer beneficially owns, in the aggregate, at least 20% of the outstanding common stock of the Company.

In the first quarter of 2005 SkyePharma purchased the outstanding stock, 11,160,000 shares, and related rights from Mike Ajnsztajn and Gaston Liebhaber. Consequently, as of March 3, 2005 SkyePharma owns approximately 49.8% of the Company's outstanding common stock.

Stock Warrants

At December 31, 2004, the Company had the following outstanding common stock

warrants to purchase its securities:

Number of Warrants Issued	Exercise Price Per Share
18,151,891	$0.50 - $4.00

These warrants were primarily issued in connection with the exchange with Astralis, LLC and the private placement offering.

NOTE 9 - STOCK OPTION PLAN

On September 10, 2001, the Company adopted its 2001 Stock Option Plan that provides for the granting of options to officers, directors, employees, and consultants. The number of shares of common stock that can be purchased under this plan is limited to 5,000,000 shares, adjustable for changes in the capital structure of the Company. No options can be granted under this plan after September 10, 2011. Options granted under this plan may be either incentive stock options or non-qualified stock options. Options terms are not to exceed 10 years. The options have limited transferability, and will be subject to various vesting provisions as determined at the date of grant. The Board of Directors or a committee thereof will determine the exercise price of options granted in accordance with the provisions of this plan. The Board has the ability to amend, suspend or terminate this plan at any time, subject to restrictions imposed by applicable law.

NOTE 9 - STOCK OPTION PLAN - (Continued)

On December 31, 2001, the Company granted two consultants options to purchase an aggregate 300,000 shares of the Company's common stock in exchange for their services. These options vest ratably, at 75,000 per year, over a four-year period commencing in 2001. The expiration terms of these options are 4 years, 3 years, 2 years and 1 year, for options vesting in 2001, 2002, 2003 and 2004, respectively. The strike price for all of these options is $2.75.

During July 2002, the Company granted 15,000 stock options with a strike price of $2.50, as compensation to a consultant.

The Company records deferred compensation when it makes compensatory stock option grants to employees, members of the Board of Directors, consultants or advisory board members. For the options granted to consultants, the amount of deferred compensation recorded is the fair value of the stock options on the grant date as determined using a Black-Scholes option-pricing model. The Company records deferred compensation as a reduction to shareholders' equity with an offsetting increase to additional paid-in capital. The Company then amortizes deferred compensation into stock-based compensation expense over the performance period, which typically coincides with the vesting period of the stock-based award.

During April 2003, the Company granted options to purchase 50,000 shares of common stock at an exercise price of $0.45 per share to one of its directors. Options to purchase 12,500 shares of common stock vested on April 4, 2003, and

options to purchase an additional 12,500 shares will vest each year thereafter for the following three years. In July 2004, 25,000 vested options were exercised.

On July 2, 2004, the Company granted options to purchase 50,000 shares of common stock at an exercise price of $1.00 per share to one of its directors. Options to purchase 12,500 shares of common stock vested on grant date and options to purchase an additional 12,500 shares will vest each year thereafter for the following three years. The term of the options is four years.

During December 2004, the Company granted options to purchase 728,000 shares of common stock at an exercise price of $0.70 per share to one of its officers. The options are vested immediately and expire in ten years.

NOTE 10 - DEFERRED COMPENSATION

The components of deferred compensation for the options granted are as follows at December 31,

	2004	2003
Balance at January 1	$ 4,822	$ 12,164
Deferred compensation recorded	--	--
Fair value adjustments	--	18,321
Amortization to stock-based compensation	(4,822)	(25,663)
Balance at December 31	$ --	$ 4,822

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NOTE 10 - DEFERRED COMPENSATION - (Continued)

Exercise prices for stock options outstanding as of December 31, 2004 and the weighted average remaining contractual life are as follows:

Exercise Prices	Options Outstanding	Weighted Average Remaining Contractual Life	Number Exercisable	Weighted Average Exercise Pric
$ 0.45	25,000	3.25 years	--	$ 0.45
$ 0.70	728,000	10 years	728,000	$ 0.70
$ 1.00	50,000	3.5 years	12,500	$ 1.00
$ 2.50 - 2.75	315,000	1.08 year	315,000	$ 2.74

In accordance with FAS 123 the fair value of the options were estimated as of the date of the grant or subsequent vesting date, or December 31, 2004 if not vested, using a Black-Scholes option-pricing model. The assumptions used in estimating the fair value of the options ranged as follows:

Volatility	100% - 130%

Risk-free interest rate	2.1% - 4.19%
Expected life	1 - 10 years
Dividend yield	--

NOTE 11 - RELATED PARTY - TRANSACTIONS/COMMITMENTS/INDEMNIFICATIONS

Patent

A founding member of the Company is the owner of a patent application, filed March 16, 2001 with the United States Patent and Trademark Office, entitled "Compositions and Methods for the Treatment and Clinical Remission of Psoriasis" (the "Invention"). On April 26, 2001, the Company, in exchange for $10, entered into an exclusive license agreement to use and exploit the Invention, the technology related thereto, and the related patent rights, including the ability to license foreign patent rights. The term of the license agreement expires on the last date of expiration of the patent or earlier date as specified in the license agreement.

During the term of the license agreement, the Company is required to pay all fees and costs relating to the filing, prosecution, and maintenance of the patent and associated rights. In addition, the Company is required to pay all reasonable attorneys' fees of the Company, or patent owner, in the pursuit of any patent infringement litigation.

SkyePharma PLC Agreements

On December 10, 2001, the Company executed three agreements with SkyePharma, a pharmaceutical company located in England.

The Company entered into a stock purchase agreement whereby SkyePharma agreed to purchase 2,000,000 shares of Series A Preferred at a price of $10 per share in five separate closings over a 13-month period commencing in December 2001 (see Note 8).

The Company entered into a technology option agreement whereby it agreed to pay SkyePharma $5,000,000 in return for the right, for 7 years, to enter into a non-exclusive license agreement with SkyePharma to utilize three drug delivery systems ($2,000,000, $2,000,000, and $1,000,000, respectively per delivery system). The royalty fee in this license

NOTE 11 - RELATED PARTY - TRANSACTIONS/COMMITMENTS/INDEMNIFICATIONS (Continued)

agreement is specified to be 5% of the net sales of any product the Company sells utilizing a SkyePharma drug delivery system. All other terms of this license agreement would need to be determined upon exercise of the option. The Company can transfer this option to another party, subject to approval by SkyePharma. This license would only allow the Company to use these delivery systems for drugs that treat two particular immunotherapies - psoriasis and leishmaniasis. The $5,000,000 fee was required to be paid on December 10, 2001 and was netted (for convenience purposes) out of the first $10,000,000 installment purchase of preferred stock by SkyePharma.

The technology option cost basis exceeded its fair value under the FAS No. 144 test as of December 31, 2004 and consequently the Company recorded an impairment

charge of $2,797,612 in relation to the option (see Note 5).

The Company entered into a services agreement whereby it paid $11,000,000 to SkyePharma in return for SkyePharma providing all development, manufacturing, pre-clinical and clinical development services for the Company's primary - second generation Psoraxine, up to the completion of Phase II clinical studies. The contract recognized that SkyePharma performed $3,000,000 of these services in the fourth quarter of 2001 and that SkyePharma will perform and be paid for the remaining $8,000,000 of services in 2002 and 2003. The payment terms for the services agreement are fixed. The Company paid $3,000,000 in 2001, $7,980,000 in 2002 and $20,000 in 2003.

The service agreement terminated on December 31, 2002. In March 2003, the Company and SkyePharma amended the original service agreement, effective January 1, 2003, to extend the term of the agreement and modify the services to be provided by SkyePharma. SkyePharma will continue to provide certain services to the Company through December 31, 2004 in consideration for payments it received from the Company during 2002 in connection with this agreement, as a prepaid expense. This prepaid amount was expensed during the remaining period of the amended service agreement, In 2004 and 2003, the Company expensed $1,007,500 and $1,007,500, respectively, in connection with the services agreement.

SkyePharma has the right of first negotiation to acquire the worldwide licensing and distribution rights to Psoraxine up to the completion of the Phase II studies. On completion of Phase II studies, Astralis will offer SkyePharma the option to acquire the worldwide licensing and distribution rights to Psoraxine. If SkyePharma does not take the option, Astralis will seek a marketing partner to fund Phase III clinical studies and to provide a sales and marketing infrastructure.

As of March 7, 2005, SkyePharma owns approximately 49.8% of the Company's outstanding common stock.

Indemnification

The Company has agreed, subject to specific provisions in the Technology Access Agreement, to indemnify SkyePharma, its directors and employees against any and all losses, claims, demands, proceedings, actions, etc. which may be brought or established against them as a result of, among other items, i) negligence of Company personnel or contractors or ii) death, personal injury or property damage or loss caused by the Company selling a product containing a SkyePharma delivery system which is defective or not merchantable. However, this indemnification does not apply to any death or personal injury arising from defects inherent in the delivery systems or technical know-how of SkyePharma licenses with the delivery system technology.

NOTE 12 - OPERATING LEASES

On March 13, 2002, the Company entered into a lease agreement for laboratory and office space. The lease period is for three years and rent is $77,500 annually. The Company also entered into a concurrent service agreement with the lessor of the laboratory space on a time and material basis.

During 2003 and 2004, the Company leased two apartments and an automobile for two different key employees, one of whom is an officer. One of the leases terminated in August 2004. As of December 31, 2004, the Company had one lease outstanding for an apartment of a key employee and one auto lease outstanding.

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NOTE 12 - OPERATING LEASES (Continued)

The Company incurred rent expense in the amount of $128,443 and $137,070 for 2004 and 2003, respectively.

The following is a schedule by year of future minimum rental payments required under operating leases, as of December 31, 2004:

Year Ending December 31:	
2005	$ 58,835
2006	1,908
2007	1,113

NOTE 13 - COMPREHENSIVE LOSS

Excluding net loss, the Company's source of comprehensive loss is from the net unrealized loss on its marketable debt securities, which are classified as available-for-sale. The following summarizes the components of comprehensive loss:

	Year Ended December 31,	
	2004	2003
Net loss to common stockholders	$(20,037,568)	$ (5,080,427)
Unrealized gain (loss) on securities:		
Unrealized gain (loss) arising during period	--	(26,245)
Reclassification adjustment for loss realized in net loss	27,698	13,728
Unrealized gain (loss), net	27,698	(12,517)
Comprehensive loss	$(20,009,870)	$ (5,092,944)

NOTE 14 - CONCENTRATIONS

The Company currently has two products that are under development. Lack of product development or customer interest could have a materially adverse effect on the Company. Further, significant changes in technology could lead to new products or services that compete with the product to be offered by the Company. These changes could materially affect the price of the Company's products or render them obsolete.

NOTE 15 - SUPPLEMENTARY DISCLOSURES OF CASH FLOW INFORMATION

The Company did not pay any interest or taxes in 2004 or 2003.

NOTE 16 - SUBSEQUENT EVENTS

In January 2005, the Company entered into an Employment Agreement with the newly hired Chief Executive Officer of the Company. The agreement is for a term of two years and will be automatically renewed for an unlimited number of additional terms of one year each unless either party provides written notice of termination at least ninety days prior to the end of such term.

NOTE 16 - SUBSEQUENT EVENTS (Continued)

In January 2005, the Company issued 100,000 shares of the Company's common stock along with 728,000 options to a newly hired officer of the Company. The options were issued with an exercise price of $0.70 per share and vest equally over four years, with a term of ten years.

On March 14, 2005, the Company issued a press release to disclose the results of its Phase II study for Psoraxine. The Phase II study of our novel immuno-stimulatory product for the treatment of Psoriasis did not meet the primary study endpoint upon completion of the treatment phase of the study thereby providing inconclusive results. In the study, Psoraxine was found to be safe and well tolerated.

The Company is currently analyzing the data from the Phase II study to understand why the results differ from the long-term improvement of the more than 2,700 patients who were treated with Psoraxine in pre-clinical studies and whether a different approach, including evaluating a longer course of therapy and/or modifications to the formulation, may yield an outcome that is more consistent with results from pre-clinical studies.